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WHAT CANADA'S PMPRB AMENDMENTS MEAN FOR PHARMA

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What Canada's PMPRB Amendments Mean for Pharma

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Pricentric Brief

- Pricentric ONE data analysts assessed the impact of Canada's forthcoming Patented Medicine Prices Review Board (PMPRB) amendments, including a reference basket shake-up, which could significantly impact medicine prices and launches in Canada going forward
- Scheduled for January 1, 2021, Canada is dropping the US and Switzerland (the only two countries with higher drug prices than Canada) and its basket will now include Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom
- Max Klietmann, Senior Consultant and Manager of EVERSANA's PriceXpress, said, "On a cursory level, the impacts in Canada are significant (~20% drop in price for the products considered)...this is a massive potential impact in Canada alone, not to mention the potential spillover effect into other markets that either reference Canada formally or look at Canadian prices as a basis for price negotiations"

The Details

Last August, Canada's Patented Medicine Prices Review Board (PMPRB) announced a set of amendments for its regulatory measures, in a bid to strengthen and modernize the country's pricing framework for patented drugs.

Following the initial proposal of the alterations, the PMPRB released its new draft guidelines in November 2019 and launched a 60-day consultation period with stakeholders and interested members of the public. The amendments, which empower the PMPRB to more strictly control drug prices and reorganize Canada's reference basket countries to include markets where drug prices are lower, received serious industry backlash, with certain pharmaceutical companies warning that Canada could experience severe launch delays, among other repercussions, if it were to adopt the proposed amendments.

In a statement, Canada's Minister of Health, Ginette Petitpas Taylor, said that the reforms are "the biggest step to lower drug prices in a generation," and that the changes "will lay the foundation" for universal drug coverage under Canada's Pharmacare program.

Role of the PMPRB

The PMPRB holds the power to challenge the list price of any patented drug, and order companies to repay some revenue. Instead of bargaining with companies to bring drug prices down, it can declare some prices to be an "illegal abuse of patent rights" and challenge drugmakers at an internal tribunal.

For the price review, at introduction, an interim maximum List Price (iMLP) ceiling is set for the sale of the patented medicine in question, according to the median international list price gathered from the reference basket of countries. Patentees must ensure that the patented medicine's gross publicly available Canadian ex-factory price (List Price) is no higher than the iMLP for the period during which it is applicable, failing which the price may be subject to additional review.

Proposed Changes

Going forward, Canada is dropping the US and Switzerland; the only two countries with higher drug prices than Canada. Now, the basket will be Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Amending the country's reference basket would allow the international reference price (IRP) to provide the PMPRB with the actual market price of medicines in Canada, as opposed to inflated list or "sticker" prices, according to the watchdog agency. On top of this, the change would ultimately let the PMPRB accurately assess whether a price is reasonable when setting a price ceiling, as the new list of countries was deemed to have more similar consumer protection priorities, economic wealth, and marketed medicines as Canada.

In the original Draft Guidelines, the PMPRB also stated that patented medicines that received a Drug Identification Number (DIN) prior to August 21, 2019 are now to be categorized as "grandfathered" products, meaning they will be subject to a different price review process than non-grandfathered products.

However, patented medicines sold in Canada prior to August 21 under the Special Access Program are not assigned a DIN and, therefore, are not grandfathered.

The body explained that the Maximum List Price for grandfathered products would be the lower of (i) the median international price across the amended list of comparator countries, referred to as the "PMPRB11" after the removal of Switzerland and the US, for which the patentee has provided information, and (ii) the price ceiling set under the current PMPRB Guidelines.

Non-grandfathered products, however, would be further divided into two categories:

- **CATEGORY I:** A medicine for which either (i) its 12-month treatment cost is greater than 50% of GDP per capita, or (ii) its estimated or actual market size (revenue) exceeds the annual Market Size Threshold of CA$ 25 million.
- **CATEGORY II:** All other patented medicines.

Following this, Category I patented medicines would be subject to two price ceilings: The Maximum List Price, based on the median international list price in the PMPRB11 and adjusted before being eventually set, annually; and the Maximum Rebated Price, based on the pharmacoeconomic value of the drug and the market size for the patented medicine. Category II medicines, however, would be subject only to the Maximum List Price.

The proposed amendments also give new, more stringent powers to the PMPRB, allowing it to now consider the cost-effectiveness of new medicines from January 1, 2021, and in some cases, the ability to force pharmaceutical companies to disclose confidential discounts to the price regulator.

Henceforth, the PMPRB will consider the opportunity cost of a medicine in the health system when evaluating whether its price is excessive, as well as considering the economic impact of paying for the drug for all patients who need it, when evaluating whether the company's pricing is excessive.

As such, the Maximum Rebated Price (MRP) of a drug would be calculated as follows:

- The Incremental Cost-Effectiveness Ratio (ICER) measured in cost per quality-adjusted life years (QALYs) for each indication of the patented medicine will be identified from the cost-utility analyses filed by the patentee
- The ICER will be compared against the applicable Pharmacoeconomic Value Threshold (PVT) of $60,000 per QALY

Also, in terms of looking at market size, the PMPRB will consider gross domestic product (GDP) and GDP per capita as indicators of what Canada and individual Canadians can afford to pay for new patented medicines.

Effects

The new reference country basket will significantly impact both the highest international price and the median international price comparison metrics, and although Canada is a relatively small market for major drugmakers,

lower prices in Canada could potentially spread into the US; a major market for pharma companies.

According to data compiled by EVERSANA analysts, the change in reference basket means that future manufacturer prices (MNF) of the 10 highest revenue drugs across all provinces in Canada could be slashed by over half in some cases.

For example, Bayer's Eylea (aflibercept), an anti-VEGF medication that's administered by an injection into the eye to treat wet age-related macular degeneration (AMD), would fall quite considerably by 21%.

MSD's immuno-oncology blockbuster, Keytruda (pembrolizumab), would also take a hit from the amendments, seeing a 10% reduction in MNF.

Drug	Current MNF Price	Future MNF Price	Percent Change
AVASTIN	$3.20	$3.05	4%
ENBREL	$5.69	$3.77	34%
ENTRESTO	$0.03	$0.03	10%
EYLEA	$507.40	$401.63	21%
HARVONI	$1.16	$0.95	19%
HUMIRA	$13.46	$10.89	19%
JANUVIA	$0.05	$0.02	55%
KEYTRUDA	$31.49	$28.41	10%
OPDIVO	$14.00	$13.52	3%
ORKAMBI	$0.38	$0.55	No upward revision (no change)

Most substantially, however, would be the 55% drop in MNF price for Januvia, another MSD drug that lowers blood sugar levels in adults with type 2 diabetes.

"We examined a selection of the top revenue generating drugs globally and applied the proposed IRP rule based on current global ex-manufacturer prices derived from Pricentric," explains Max Klietmann, Senior Consultant and Manager of EVERSANA's PriceXpress.

"On a cursory level, the impacts in Canada are significant (~20% drop in price for the products considered). This is a massive potential impact in Canada alone, not to mention the potential spillover effect into other markets that either reference Canada formally or look at Canadian prices as a basis for price negotiations."

Despite the country's federal government saying its amendments will not impact the way pharma companies view Canada as a business market, the sizeable margins mean that some manufacturers would have to reconsider launching certain drugs in Canada. A company's sustainability relies heavily on keeping profitability attractive to investors, and the changes would reduce Canada's appeal as a jurisdiction for manufacturers to seek regulatory and reimbursement approval for potential new drugs.

Industry Feedback

Multiple pharmaceutical executives have stated that they expect the amendments to the PMPRB to have a negative impact on their Canada business plan, according to results from a survey conducted by a Canadian not-for-profit life sciences organization.

The survey found the most significant anticipated impact will most likely be on product launches, commercialization, and the supply of current products in the Canadian market, followed by clinical research, patient support programs, compassionate use access programs, and manufacturing.

Respondents also said that drug launches for biologic medicines and oncology, rare disease, immunology, cell and gene therapy, and rheumatology drugs will be most affected by the amendments.

The effects are already being felt, as according to the study, some companies have already stopped plans to launch new medicines in Canada, with one company indicating that it may be forced to withdraw a first-line therapy because the new pricing formula will place the Canadian price far below those found in other developed countries.

In addition to the survey, the Canadian Organization for Rare Disorders (CORD) warned that the new maximum price calculations will slash prices so low, in some cases up to 40% and 90%, that no new medicines will come to market in Canada.

Where It Stands

Speaking recently at ISPOR, Director of Policy and Economic Analysis at the PMPRB, Tanya Potashnik pointed to evidence that many countries outperform Canada in terms of earlier drug launch times, despite having lower prices. She added that price is actually a weak determinate of time of launch while market size, wealth of country, and expenditure are stronger determinants.

Nevertheless, PMPRB heard industry feedback. In a statement issued in February, PMPRB said, "The draft regulations remain just that—a draft. The PMPRB is contemplating significant changes to the document in light of stakeholder feedback."

Some patient advocacy groups have expressed their worry over being able to access the most innovative treatments poised to come to market, with Cystic Fibrosis Canada publishing a statement calling for the PMPRB to cease the plan, as according to the charity, those that suffer from cystic fibrosis are immuno-compromised, and 85 per cent will die from respiratory failure—that is, before the effects of COVID-19 are also considered.

The organization is concerned that the changes will block access to a therapy that is being hailed as the single biggest advancement in treating cystic fibrosis, while the therapy has been fast-tracked for approval in the United States, United Kingdom, and Europe.

Additionally, on April 2, the PMPRB's Chairperson noted in a statement that in view of COVID-19, the organization would reassess the intended next steps closer to the date of their publication. There has, however, not been any update on potential delays or disruptions since, so pharma should anticipate the implementation of this new practice according to schedule.

More recently, on June 1 it was officially announced that the amendments will be delayed by six months and come into force on January 1, 2021, as opposed to the initially proposed July 1, 2020, due to COVID-19.

How EVERSANA Can Help

EVERSANA is actively engaging with several clients to assess potential global price impacts resulting from this legislative change and is able to offer high-level impact studies via PriceXpress, our tactical price consulting and analysis offering.

"These are very nebulous and challenging times for the industry," says Max Klietmann. "We've found that our clients are in a better position to make strategic decisions when armed with a holistic perspective of where potential impacts could manifest themselves and a solid mitigation plan."