While Friday’s announcement of amendments to the Patented Medicines Regulations (the "PMR") may not have introduced any surprises, it did highlight the considerable uncertainty facing patentees selling medicines in Canada.

A closer look at the regulatory language, along with the accompanying Regulatory Impact Analysis Statement ("RIAS") and Cost-Benefit Analysis, highlights the significant work that remains to ensure a fair, predictable, and transparent pricing system is developed in Canada.

Overview of the Changes

There are three broad categories of changes contemplated in the amended PMR:

1. New regulatory factors that must be considered when determining if a medicine’s price is "excessive";
2. Overhaul of the basket of international comparator countries; and
3. Focus on the "actual" price of the medicine, net of all adjustments, discounts, and rebates.

The government is projecting $8.8 billion in savings as a result of the amendments to the PMR over the next 10 years, with each year providing increasingly greater savings over the last. Of the $8.8 billion in projected savings, the government predicts that the new regulatory factors will
have the greatest benefit (savings of $3.8 billion), followed by the change to the basket of countries (savings of $2.8 billion), and finally the use of actual revenues net of all adjustments (savings of $2.0 billion).

**Which Medicines are Impacted?**

All medicines sold in Canada are subject to the change in comparator countries, and the requirement to report the "actual" price of the medicine net of all adjustments, discounts, and rebates. However, medicines which obtain a drug identification number (DIN) prior to the amendments to the PMR being published in the *Canada Gazette*, Part II (set for August 21, 2019) will be excluded from the new price consideration factors and additional reporting obligations regarding those factors. It is unclear if a patentee (broadly defined as anyone deriving benefit from the patent, including licencees) who would otherwise be excluded by reason of their DIN date could seek to rely upon these additional factors if they supported their pricing being below the excessive price ceiling.

Notably, by only excluding products which obtained a DIN prior to August 21, 2019, medicines sold under the Special Access Program, which are not assigned a DIN, will be subject to the full scope of the PMR. In contrast, by not relying upon the issuance of an NOC, existing medicines which obtain new indications (but not a new DIN) could see significant changes to their market position without any corresponding change to their PMPRB requirements.

The use of the date at which the DIN is assigned is an interesting decision, as it is a date mostly out of the patentee's control. In contrast to a regulatory submission date, a patentee is limited in its ability to control when a DIN will be assigned as it is dependent on Health Canada's review process. The delay between announcement of the amendments on August 9, 2019 and the impact of the August 21, 2019 effective date is largely immaterial, given a patentee's potential reaction in the interim is extremely limited.

The amendments to the PMR continue the recent trend of regulations under the Patent Act relying upon dates largely outside of the patentee's control. For example, under the Certificate for Supplementary Protection Regulations certain conflict proceedings are addressed by reference to the patent's issue date. However, the patentee has limited control over when their patent will issue, in contrast to the patent's filing date, making it an uncertain method of determining substantive legal rights and obligations.

**New Schedule of International Comparator Countries**
The change with the widest scope is the adjustment to the schedule of international comparator countries. Currently, the price of a medicine is compared against the "PMPRB7" - the United States, the United Kingdom, France, Germany, Switzerland, Italy, and Sweden.

Starting July 1, 2020, international comparisons will be made against the "PMPRB11" - Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

In addition to the addition of a number of new countries, a notable change is the removal of the United States and Switzerland. These two countries were generally regarded as having high medicine prices, and criticized as resulting in an otherwise inflated non-excessive price ceiling. South Korea was initially proposed in the list of new countries, however it was removed from the final schedule of international comparator countries.

As a result of the change to the schedule of international comparator countries, as of July 1, 2020 all existing comparisons and test performed by the PMPRB will be done against the PMPRB11, not the PMPRB7. This will be the case no matter when a medicine obtained its DIN.

Notably, there is no transitional provisions within the amendments to the PMR. As a result, the PMPRB11 will immediately replace the PMPRB7 as of July 1, 2020. It is unclear what impact this change will have on sales made prior to July 1, 2020. While there is a general presumption that legislative changes are not applied retroactively, clarification should be sought during the drafting of the PMPRB Guidelines to ensure that the PMPRB11 is not used as the comparator against sales made prior to July 1, 2020.

**Reporting "Actual" Prices**

A key change to the reporting requirements is that the patentee must report the "actual" price of the medicine. In other words, ex-factory prices are no longer considered, and instead the patentee must report the price and revenues net of all price adjustments such as discounts, rebates, or free goods and services. As with the expanded group of comparator countries, this change impacts all reportable medicines, no matter the date they obtained their DIN.

**Reporting prices net of all rebates and discounts**

The RIAS states that by reviewing the actual price of the medicine, the PMPRB will be able to better calculate average transaction prices to inform existing factors. Additionally, the RIAS states that the actual price, which would be lower than the ex-factory price, will assist patentees in complying with the lower price ceilings that are expected by reason of the new
pricing factors.

Under the amendments to the PMR, the patentee is not required to disclose the existence or specifics of any confidential pricing agreement or rebate. Instead, the patentee is only required to provide:

1. the average price per package, net of all adjustments; and
2. the net revenues for the medicine.

The RIAS specifically notes that a patentee is not being required to report any specific confidential information or agreement. Instead the patentee "will only need to report the total net revenues for the medicine, the number of units sold for the medicine, and the average transaction price for any market in Canada, without providing any information on the size or existence of third party rebates."

However, it is unclear how the PMPRB will review this information, given the only way to accurately confirm net pricing is by reference to the gross revenues, units sold, and rebates and adjustments provided. It is therefore unclear if the PMPRB will attempt to require the disclosure of anything beyond the net value calculated by the patentee, for the purposes of auditing the patentee's stated net price.

Given the RIAS' clear language that the existence and specifics of confidential agreements are not required to be disclosed, it appears the PMPRB may be required to take the net values as reported by the patentee, without the ability to request supporting documentation. At minimum, the RIAS is clear that the patentee is permitted to protect the existence and specifics of any third-party agreements. Again, this is expected to be the subject of much discussion moving forward in developing the updated PMPRB Guidelines.

How the net prices will be used by the PMPRB

The manner in which the PMPRB will utilize the "actual" prices of a medicine is also uncertain. Notably, the federal government has projected $2 billion in savings by reason of reporting the actual prices of medicines, clearly believing that this change will reduce non-excessive price ceilings set by the PMPRB. However, there are several potential impediments to their use that could limit potential savings.

Under the PMPRB's current analysis, prices are compared to sales in other countries (soon to be the PMPRB11), or to the prices of other Canadian medicines in the same therapeutic class. Currently, the PMPRB relies upon a comparison to prices in other countries as reported by the patentee for the international comparator, and for therapeutic class comparison relies upon
publically available information.

The changes to the reporting requirements in the amended PMR will now require the patentee to report net prices only for Canadian sales. As a result, the comparison to prices in other countries would be comparing Canadian net prices against the (typically higher) ex-factory prices in the PMPRB11. Therefore, in the absence of a re-working of the international price comparison tests, Canadian prices would have a better chance of being below the excessive price ceiling due to the ability to rely upon discounts, rebates, and other adjustments for their Canadian price. This appears at odds with the federal government's projected savings.

With regard to the Therapeutic Class Comparison ("TCC") Test, it is unclear how the PMPRB will rely upon net prices of alternative products. Currently, the TCC Test relies upon public prices from various Canadian sources such as distributors or formularies. The PMR RIAS, as well as the Cost-Benefit Analysis, state that the actual prices reported by patentees will be used to provide a (presumably lower) therapeutic price ceiling for new drug entrants. While this would explain the government's projected savings from the amendments, it is unclear the extent that the PMPRB is legally permitted to rely upon this confidential information for the purpose of the TCC Test.

The Patent Act states that any pricing information provided to the PMPRB is privileged, and cannot be disclosed to another party (section 87). The PMPRB is only permitted to use this information to inform specific government officials, and for the purposes of the PMPRB's yearly report. The Patent Act does not appear to permit use of this confidential information for the purposes of establishing a price ceiling for a therapeutic class.

Presumably, the PMPRB believes it can rely upon this privileged information to internally set a price ceiling for a therapeutic class, provided it does not disclose the specific confidential information to third parties. However, this could result in a patentee being subject to pricing restriction based upon secret information that it cannot have access to. While it may be possible for the PMPRB to disclose a non-excessive price ceiling that it derived from confidential information without being in violation of the Patent Act, the limited disclosure to the patentee would impact the patentee's ability to fully vet any of the PMPRB's calculations, or challenge any inconsistencies. This would result in significant problems of due process in any hearing before the Board. Additionally, for small therapeutic classes the knowledge of the public list prices, along with the disclosure of PMPRB's non-excessive price ceiling for that class, could result in an effective disclosure of a party's privileged pricing information.

Finally, absent the PMPRB publishing the new non-excessive price ceilings for any given therapeutic class, it will be difficult for a patentee to predict any application of the TCC Test until such a time as the PMPRB institutes a pricing review given its reliance on secret information.
Ultimately, this will reduce transparency and predictability in the process.

The use of confidential net pricing by the PMPRB is expected to be a topic of significant discussion and debate as the PMPRB Guidelines are developed.

New Price Analysis Factors

The largest overhaul applies to all medicines sold in Canada except those who obtained their DIN prior to August 21, 2019. These amendments provide additional factors that the PMPRB must consider when determining whether or not a medicine is being sold at an excessive price. Specifically, the PMPRB must now also consider:

1. The medicine's pharmacoeconomic value to patients;
2. The size of the market for the medicine in Canada; and
3. Canada's GDP and GDP per capita.

Pharmacoeconomics

The PMPRB must now consider a medicine's pharmacoeconomics when determining if the price is excessive. The focus will be on the incremental cost-effective ratios (ICERs) which examines a medicine's cost per Quality Adjusted Life Year (QALY). According to the RIAS, this will permit the PMPRB to consider the opportunity cost of the new medicine when replacing an existing treatment. Specifics of how pharmacoeconomics will be considered by the PMPRB have not been set out.

As the PMPRB will now be relying upon pharmacoeconomics, there is an additional reporting requirement on patentees to submit any cost-utility analysis prepared by a publicly funded Canadian organization, if published and communicated to the patentee, which utilizes a cost per QALY for each indication. This would generally capture CADTH (both CDR and pCODR), and INESSS submissions. The patentee must also submit any information that was redacted from the public version published by these organizations. Again, it is unclear how the PMPRB will use this confidential information, and whether such use is restricted by section 87 of the Patent Act.

While there is an obligation on the patentee to report cost-utility analysis only from publicly funded entities, there is no equivalent limitation regarding what the PMPRB must rely upon in determining if a price is excessive. As a result, it appears that additional pharmacoeconomic data could be submitted by the patentee, such as analysis from private firms, and this information would have to be taken into consideration by the PMPRB.

There are a few notable uncertainties regarding reliance on pharmacoeconomics when
determining if a price is excessive. In addition to the weight of such an analysis, the PMR does not speak to:

1. Situations where there is a significant discrepancy in the cost per QALY in different pharmacoeconomic analyses, or where the patentee wishes to dispute the cost per QALY assessment developed by a public entity;
2. Situations where the patentee wishes to rely upon other pharmacoeconomic analysis other than those performed by publicly funded organizations; and
3. Situations where the company that made the pharmacoeconomic submission is not the "patentee" for the purposes of the PMPRB's analysis.

Additionally, the requirement for reporting pharmacoeconomics is dependent on whether the medicine's 12-month (pro-rated) cost is greater than or equal to 50% of Canada's GDP per capita at the time of publication of the analysis. However, GDP per capita is not an official number that is reported daily or easily available from an official source, leading to potential uncertainty of whether a drug meets this threshold. It is unclear if the PMPRB will post a GDP per capita for the purposes of this section, or leave it to the patentee's best judgment in determining whether or not to provide this information. Finally, it is unclear what the PMPRB will consider to be a medicine's "cost" for the purposes of any reporting requirements (e.g. list-price or net price), aside from the fact it is pro-rated over twelve-months.

The size of the market

The PMPRB will also consider the size of the market for the medicine when determining whether a price is excessive. In other words, whether a medicine is sold at an excessive price or not will be impacted by the number of sales made. The RIAS states that the basis for this requirement is that market size could result in displacement of more cost effective technologies. However, it is unclear to what extent the displacement and opportunity cost differs from what is already considered in any pharmacoeconomic analysis.

The possible impact of the size of the market leads to the significant uncertainty in the PMR, and is likely to be the source of significant discussion and debate when the PMPRB Guidelines are being amended. This factor could result in low-price but high volume medicines having different considerations from high-price but low volume medicines (such as rare disease treatments).

It is unclear how the PMPRB will utilize the size of the market in determining an excessive price. The Cost-Benefit Analysis assumes that the PMPRB will develop market impact tests for medicines likely to pose affordability challenges for insurers due to their market size.
Additionally, the RIAS states that the size of the market will allow the PMPRB to reassess the price over time as their market expands or contracts.

Ultimately, significant clarification of the role of the market size factor will be required for the amended PMPRB Guidelines to provide any level of certainty to a patentee.

**Canada's GDP and GDP per capita**

The RIAS is equally light on details for how Canada's GDP (and GDP per capita) will impact the determination of whether a medicine's price is excessive. The RIAS references GDP growth in a given year as reflective of what the market can afford to pay for new patented medicines. The Cost-Benefit Analysis, meanwhile, refers to Canada's GDP growth as being reflective of the maximum revenue threshold of all new medicines to be introduced in a given year.

Specifically, the Cost-Benefit Analysis notes that the GDP growth will be used to set a threshold for new medicines introduced in a given year, with medicines having total revenues in excess of that threshold seeing a reduction in price. As a result, it appears that the determination of whether or not a drug's price is "excessive" will be dependent on factors completely out of the patentee's control.

There are a number of uncertainties that arise surrounding the implementation of this factor. Reliance on Canada's GDP in determining pricing adds a variable that cannot be controlled by the patentee, and could be applied retrospectively only once the numbers are later known. It will be very difficult for a patentee to determine pricing based upon unknown factors such as the strength of Canada's economy, the number of drugs launching in a given year, and the revenues of those other drugs.

Again, significant clarification by the PMPRB Guidelines will be required to provide any degree of certainty and predictability for a patentee in how this factor will be applied.

**Next Steps**

The amended PMR will be posted in the Canada Gazette, Part II, on August 21, 2019. The PMPRB has also posted some Questions and Answers addressing the amended PMR, including discussion of their next steps. The PMPRB has stated that consultation on the new PMPRB Guidelines will begin in advance of the July 1, 2020 implementation date, with a draft of the PMPRB Guidelines expected to be published this fall. However, there were no specifics of what those consultations would involve, nor what degree of modification to the PMPRB Guidelines are expected.
As discussed above, there are significant uncertainties in language of the PMR, including how these new factors will be considered, and significant discretion appears to have been left to the PMPRB in determining how it will approach its amended mandate. Absent proper clarification on how the PMPRB will consider these new factors by way of consultation on the PMPRB Guidelines, there will be a significant lack of predictability regarding an acceptable price for medicines in Canada which will negatively impact a patentee’s decision to launch new products.

A tense consultation period is expected as the July 1, 2020 implementation date approaches. Significant debate surrounding early decisions under the new PMPRB Guidelines, including judicial review of early decisions, should be expected by the industry.
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