Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

The Patented Medicine Prices Review Board
and its role in our healthcare system

Notes for an Address by
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to

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Opening remarks

Thank you for inviting me to speak to you today. I am very pleased to be here and to have the opportunity to give this presentation as well as meet with you in this informal setting.

Summary of my talk today

As you know, I am still relatively new to the role of Chair, although I have been with the Board for several years. They have been interesting years. The mandate of the Board is one that is meaningful for me because of its critical role in the health care system broadly and its impact on consumers.

Today, I will discuss the following:

- The PMPRB's role and mandate within a broader health policy agenda
- The environment in which I work as Chair of the Board
- The Board's Guidelines
- Emerging realities
- Considerations moving forward

Role and mandate within the broader health policy agenda

The Board has a dual mandate. That said, it is not usually the "reporting side" of that mandate that is of interest to an audience like this one. Rather, it is the role as regulator. The mandate of the Board is clear and reflects the policy of the Conservative Government of the day. That Government was seeking to increase research and development by Pharma in Canada, to strengthen intellectual property protection while ensuring that consumers were protected from possible excessive prices for patented medicines. This was the role given to the PMPRB – to protect consumers from possible excessive prices.

Some 25 years later, the Board's mandate has not changed. Furthermore, I must note that the Board's consumer protection role was confirmed by the Supreme Court of Canada last January in the Celgene/Thalomid case.

So, the mandate is clear and remains in place. How then does it fit in the broader policy agenda? And what is the current environment – 25 five years later?

The Federal Government has a limited role in health care policy, as you know. We all know there is a jurisdictional split of responsibilities between the Federal Government and the Provinces and Territories. Some of you are no doubt aware that discussions have already begun between governments on a new health accord. What we do not yet know is what role this Government – at the federal level – will play in the years to come. Just how active will it be in policy making or in influencing health care policies and the implementation of these policies?

That said, if we look at the numbers, it is hard to imagine that policy makers at all levels of government, including the federal level, would not want to maintain a role in regulating the cost of drugs. As an essential element of the Canadian healthcare system, drugs are a key driver of spending: Canada spent $31.1 billion on drugs in 2010 – surpassed only by $55.3 billion spent on hospitals.

The Board's framework, which aims to ensure that Canadians do not pay excessive prices, contributes to the bottom line – for public and private payers, and for the cash-paying customer. The framework addresses affordability for all consumers and, in this way, supports the important goal of accessible drug products.

As Chair of the Board, I believe ensuring the framework has a positive impact for consumers is paramount.

Our environment

I now want to speak a bit about the environment in which the Board and I, as Chair, operate. We are, as you know, a part-time Board. As Chair, I am both the CEO, and, when serving on a hearing panel, an adjudicator. This, in and of itself, can be challenging.

The Board, as a whole, is not bound by the decisions of a hearing panel – comprised of at least two Board members. In other words, when a panel considers a matter, it is considering the particular case before it – the particular circumstances. The panel looks to the Guidelines and must decide if application of the Guidelines is reasonable and appropriate to the circumstances, or if the circumstances require a departure from the Guidelines.

Situations can arise that are not contemplated by the Guidelines. Or, as was discussed in the decision in the Adderall XR matter, changes in the market place could give rise to situations that are no longer covered by the Guidelines.

The staff has, therefore, developed a practice of seeking direction from the Board as a whole when needed, for example after decision by a panel. A direction can follow which means a change to the text of the Guidelines. We rely on staff and, specifically, on senior staff, to apply the regime, to interpret and apply the Board's Guidelines, and to ensure that the Board can be responsive to changes.

And there have been changes. Over the past five years, we have seen important changes, domestically and internationally. Distribution practices have evolved as have sales models. Patentees have also introduced different types of benefit programs, while new types of drugs have reached the market.

Public payers employ strategies to decrease their bottom line – the most recent being the changes introduced for the reimbursement of generic drugs. Other countries are also adopting price control policies and voting new legislation.

Guidelines

I will now turn to the Board's Guidelines.

The Guidelines aim to provide a structure for the necessary particularization and integration of the general factors listed in section 85 of the *Patent Act*, to provide fairness through consistent treatment among patentees, and to give patentees guidance on the process that will be used to establish the price ceiling – at introduction and at the time of the yearly review.

The latest review of our Guidelines was about 5 years in the making. I am grateful to many of you who participated in our consultation process. Although they came into force in January 2010, the revised Guidelines are still quite new – we are still learning. The one area that has received the most support and, which I feel was indeed the right change, is the new level of "moderate therapeutic improvement". Drug products that represent incremental innovation – which often are a very positive change for patients – now benefit from a pricing premium. This is an aspect of the revised Guidelines that is working well. This amendment was adopted to recognize and reward innovation appropriately within our regulatory framework.

I mentioned the Adderall XR case earlier. It is, in fact, this very case that led to the introduction of "moderate therapeutic improvement" in the Guidelines. In that case, the Panel concluded that Adderall XR provided a level of improvement over the multiple daily dose of the medicine worth recognizing. It is from this decision that flow the current price tests for the "moderate therapeutic improvement" category.

With regard to a few other elements of the Guidelines, the Board determined it best to monitor the changes before proceeding with full implementation. The intent is to make final decisions on these elements in December of this year. An example is the "any market review". This new element of the Guidelines requires a review of prices in all markets at introduction and for each yearly review. This, I believe, represents a laudable policy intent – to ensure that no market pays an excessive price, whether the market is a particular province or area of distribution, for example, the hospital class of customer.

The challenge arises when working to integrate this element with others in the Guidelines, like the DIP methodology. It would also seem to be an element that can be very resource intensive – in a time when we are looking ahead at decreasing resources and focusing on areas of priority. This is but one example of an area that the Board is monitoring and which it will decide whether to fully implement in the coming months.

I want to assure you that the Board's intention is that the Guidelines be responsive to changes in the environment that it regulates, in an appropriate timeframe. The Board will adjust or amend its Guidelines, as needed, in consultation with stakeholders.

To that end, we have adopted a plan to monitor the major changes to the Guidelines. The plan is available on our website.

Before concluding my remarks and giving you an opportunity to ask questions, I want to share, briefly, my thoughts on emerging realities and moving forward.

Emerging realities

There have been a number of notable changes within the industry, including domestic and international pricing and reimbursement policies. To name a few:

- The patent cliff of 2014 (representing a potential 7.4 Billion dollars in sales of patented drugs to generics), a figure quoted from IMS Brogan
- Decreased sales growth for Pharma in Canada this past year (as noted in our Annual Report)
- Continued efforts by payers to decrease overall drug expenditure budgets (there is ongoing talk of provincial and territorial buying groups and pan-Canadian purchasing)
- Changing distribution channels as well as pricing and business models within the pharma industry broadly
- Price reduction and control policies in countries such as the UK and Germany.

We are also seeing changes in the products themselves. An area to watch with interest is the entry of the latest technologies and therapies, including new biologics and nanotech, as well as personalized or niche medicines.

And how can any of us forget the changes in our economic environment which has had, and will no doubt continue to have, such a great impact? At the federal level, we are certainly in a time of fiscal restraint and budget reduction exercises.

Considerations as the Board moves forward

Finally, the Board is keenly aware of the changes occurring in its operating environment. To use a famous quote: "Just because everything is different, does not mean anything has changed." (Quote by Irene Peter)

Drugs are a critical component of our health care system. We all hope that, when needed, therapies can be accessed at affordable prices. And so, the Board's mandate remains important.

Our main objective is to effectively deliver on our mandate to ensure that prices of patented medicines are not excessive. We need to consider how to best implement this regime, in a way that is supportive of other policy initiatives that may be adopted by payers, for example. The regime is not meant to be punitive – in my view, it puts consumer interests first, while recognizing the value that innovative medicines offer to patients.

These are some of the Board's considerations as it moves forward.

Thank you very much for your attention and I would be happy, if time permits, to take any questions.