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October 24, 2016

Mr. Doug Clark
Executive Director
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa ON K1P 1C1

Re: PMPRB Guidelines Modernization Discussion Paper

Dear Mr. Clark:

On behalf of Valeant Canada, I am pleased to submit our response to the series of questions posed within the Discussion Paper released in June 2016.

Valeant Canada will work cooperatively with the Board and stakeholders to ensure we assist the Board in refining its mandate in support of reasoned and sound pharmaceutical policy.

As you will note in our response, Valeant Canada has chosen to highlight a different and perhaps complimentary adjunct to the current method of reporting on research & development. With significant on-the-ground assets in Canada, and with its related economic inputs to our economy, Valeant Canada is uniquely positioned to suggest that certain other metrics beyond research & development be used in assessing the performance of a pharmaceutical company. While we recognize the *Patent Act* does not accommodate such a method of assessment at this time, we nonetheless feel it is an important issue to consider within these broader discussions.

In addition, Valeant Canada is participating in the Minister of Innovation, Science & Economic Growth discussion on making Canada a world leader in innovation. Valeant Canada is again uniquely positioned to play a significant role in those discussions and we are looking forward to finding the complimentary balance between the Board's mandate and Guidelines with that of the federal government's ambitious innovation plans.

Valeant Canada looks forward to participating in the next phases of this discussion.

Yours sincerely,

Sebastien Beauchamp
Executive Director, Patient Access & Government Affairs
Valeant Canada LP

Guidelines Modernization & Consultation paper Response

Thank you for the opportunity to participate in the consultation process to enable modernization to the PMPRB's Guidelines. Valeant Canada is responding in the spirit of cooperation and in light of the much broader policy discussion on which this issue should rest. That is to say, the PMPRB's jurisdiction on excessive pricing of patented medicines is one small part of a much broader discussion that needs to occur for the sake of the end-users of drug therapy: patients. We must take the opportunity to view this exercise through a much wider lens to consider other factors such as ensuring access to appropriate therapies, appropriate use of those therapies, prescribing behaviours, and patient outcomes. All of these factors must be considered in this consultative process as they all relate back to the issue of price, cost, and affordability.

About Valeant Canada

Valeant Canada is committed to bringing quality products to Canadians that benefit their wellbeing.

Our commitment to patient health can be felt in pharmacies, healthcare practices and hospitals across the country, as Valeant Canada manufacturers, markets and distributes a wide selection of pharmaceutical products. A strong commercial infrastructure enables us to provide new, cutting-edge, effective pharmaceutical, eye health and consumer products to Canadians, and to export markets abroad.

While we are proud to offer Canadians a wide range of quality products, we are equally proud to have the best employees working for us across the country, and at our global headquarters in Laval, Quebec. In Canada, the company has approximately 1000 employees based out of Laval, Quebec (International Headquarters and manufacturing facility); Vaughan, Ontario (Bausch + Lomb and Consumer Products Division); Steinbach, Manitoba (manufacturing facility); and in field-based roles across the country.

From 2013-2015 alone, Valeant Canada has contributed to the local economy by $525M.

Valeant Canada has a diverse product portfolio in several therapeutic areas, including Cardiovascular Disease, Neurology and Dermatology, and ophthalmology and we continue to expand these areas with new offerings and local collaborations. And, as leaders in new research and development in dermatology, Valeant Canada is also proud to have established an R&D Centre of Excellence for consumer dermatology in Laval, Quebec.

We believe in finding new and better health care solutions that are timely, innovative, effective, and help sustain the health care system. We invest in people. We make swift decisions and work quickly to keep up with the changing market while not compromising on quality. Delivering value to our stakeholders while delivering safe and effective products to Canadians is at the heart of everything we do.

Question #1

What does the word "excessive" mean to you when you think about drug pricing in Canada today? For example:

a. *Should a drug that costs more annually than certain agreed upon economic metric be considered potentially excessively priced?*
b. *Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?*
c. *In considering the above two questions, does it matter to you if a very costly drug only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada?*
d. *Conversely, if a drug's price is below an agreed upon metric and in line with other drugs that treat the same disease, should it be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada?*
e. *What economic considerations should inform a determination of whether a drug is potentially excessively priced?*

Response

a. With respect, Valeant sees the Consultation paper and discussion questions interchanging the Board's jurisdictional term of "excessive" with non-synonymous terms such as, "cost," "affordable," and "spending." We see this as the possible influence of government payers expressing concern to the Board about annual drug expenditures, which is understandable, but at the same time somewhat unreasonable given the flattening of F/T/P drug-cost curves. The term "excessive" from the Board's jurisdictional perspective is fundamentally different than relative terms like "cost" or "affordable." An excessive price is one thing, the annual volume of a particular drug and its annual cost in another. What drives volume (which then determines annual cost) falls into the broader and important context surrounding drug use and prescribing behaviours. Controlling the P or price part of the cost equation [TC (total cost) = P (price) x V (volume)] is only part of the answer. In fact, some may argue the issue isn't so much the price part of the equation but rather the volume part. We share in the view that a disproportionate amount of resources are being expensed on price issues and little to nothing being spent on volume issues. In other cases, the low volume of a drug utilization seem to be explaining to high price attached to it, which is an example at the heart of this discussion.

b. This question is rather broad and raises other related questions. For example, is that particular drug more efficacious or of higher therapeutic value? What are the

downstream effects of that drug if it is more efficacious? Is it offsetting other costs in the healthcare system? What are those cost-offsets? Is a patient's quality of life increased? These are reasonable questions to consider of drugs currently on formulary. For new entrants, the complex and burdensome drug review process in Canada largely estops this type of scenario in that CDEC's recommendation and indeed pCPA would very likely block such a listing.

c. No

d. No

e. There are many factors to consider not least of which is the time it takes a manufacturer to have a drug listed relative to its patent term. As time-to-list continues to be compressed with lengthy processes for approval, the time to regain investment on the product is shortened thereby putting upward pressure on price. There is also perhaps a broader economic determinant when considering whether a price is excessive. For example, what if the manufacturer has significant assets in Canada, say, it manufactures and exports in excess of $2B of product creating good paying jobs and delivering significant economic inputs to the Canadian economy. Should that pharma company be treated differently than others with little or no similar assets?

Question #2

Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?

Response

No. Confidential rebates are used extensively in developed nations and are often based on different jurisdictional considerations such as volume, a unique population subset, or reimbursement/use criteria applied by that jurisdiction. Perhaps the question to be asked is whether there is a determinant that is in a unique Canadian context. That is to say, what other factors exist with manufacturers that can determine pricing? Valeant Canada is suggesting that the Canadian investment level also be that determinant in determining the price ceiling of a new drug coming to the Canadian market, in order to stimulate the economy, increase the number of new manufacturing jobs and therefore, reward the Canadian investments in a tangible manner. This is also in line with the recently announced Innovation agenda, by the Minister of Innovation, Science and Economic Development.

Question #3

In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?

Response

All aspects of Section 85 are important. Again, the Canadian investment level can also be a factor in determining the price ceiling of new or existing drugs in the Canadian market, in order to stimulate the economy, increase the number of new manufacturing jobs and therefore, reward the Canadian investments in a tangible manner, notwithstanding the price comparison with the PMPRB7 countries. In fact, the aspect of the guidelines around *"Any market" price review* (Guidelines Modification presentation from April 2016, slide 16) could include the United States as a comparator, for the companies that do invest in Canada in a formal manner, through local manufacturing and/or R&D up to a certain percentage of the annual gross sales that would need to be defined.

Question #4

Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e., the US, the UK, Sweden, Switzerland, Germany, France and Italy)?

Response

It is important for Canada to remain a competitive market and to make sure we keep attracting more investments. Therefore, setting the price ceiling to the high end of the PMPRB7 countries is critical. What is important here is to have prices in Canada that continue to incent manufactures with measurable and qualified assets in the Canadian economy to stay and invest. In any event, prices are not necessarily always at the maximum non-excessive price due to the oversight of HTA bodies which consider a number of factors that affect price in a downward projection.

Question #5

Does the amount of research and development that the pharmaceutical industry conducts in Canada relative to these other countries impact your answer to the above question and if so, why?

Response

Research & development is but one measure. What about manufacturers who additionally invest in production assets, employment, exports and other significant inputs to the Canadian economy? Such activity should not be lost in the broader discussion as they are significant and may in fact be a possible price measurement tool.

Question #6

What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the outset and address questions of high relative prices, market dynamics and affordability?

Response

This is a question that we are not in a position to respond in detail. However, some consideration could be given to the Board segmenting its categorization into 2 parts: 1) so called "expensive" new patent drugs for unique or specialized treatments; and 2) all others, which have nominal price issues and should frankly not consume the Board's jurisdictional time. On this same theme, some may argue that for existing patented drugs the Board shift those and others to a reactive system of price-watching similar to that for vet and OTC drugs.

Question #7

Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?

Response

In light of our response under Question #5, we believe that manufacturers with measurable and qualified assets that contribute to the Canadian economy, in other words, companies that have on-the-ground manufacturing, on-shoring of production (tech-transfers) and employ Canadians with good paying jobs (to name a few) could be given preferential price treatment.

Question #8

Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?

Response

No. In the absence of other favourable mitigation, this defies fair business practices as a manufacturer's costs rise with time, not diminish. To suggest that there should be an inverse relationship between cost and price is simply not reasonable and could play a significant role in destroying Canada's desire to be an innovation leader according to the federal government's recent stated ambition http://news.gc.ca/web/article-en.do?nid=1084439. To provide a clear example, if a product has been on the Canadian market for several years and the price decreases in one of the PMPRB7 countries, a European country in this case, it doesn't seem like a fair practice to impact negatively the price of that product in the Canadian market through way of an investigation and potential VCU.

Question #9

Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?

Response

No. It is interesting the view governments take of the pharmaceutical industry relative to other industries with whom they transact. The Provinces and Territories have a plethora of allowed or applied discriminatory practices on price and consumer availability in all sorts of industries, yet somehow the pharmaceutical industry achieves special and disproportionate attention. As suggested in Response #8, careful thought must be given to the effect on manufacturers.

Question #10

Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?

Response

Yes. At the top of the list would be the filing burden and what is referred to as, "the 4th decimal-point calculation." In the past, the Board said it would like to take steps to lower the filing burden. We agree with this objective as it would relieve Board staff and manufacturers of some of the burden without materially affecting the Board's objectives. Board staff could then focus on other activities.

Also, we do not support new competitor pricing based on the ATP of the first entrant, as determined from IMS's Canadian Drug Store & Hospital price audit. This practice is problematic at many levels not least of which is that it is a disincentive to manufactures to come to market. For a manufacture with measurable and qualified assets in Canada, this could mean no job creation or even job loss as a financial response to this effect.

Question #11

Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?

Response

Applying it only to all patented drugs would amount to an unfair business practice. Manufacturers applied and were processed based on certain terms and metrics. To retroactively change those would be, as was stated, unfair and goes to the disincentive issue. Imagine the response if government attempted to retroactively price diminish or change the terms of engagement on other industries. This would most probably have a negative effect on the R&D investments, as well as putting in jeopardy all the recent manufacturing investments that were made to compete with India and China, where the labor cost is much lower than in Canada.

Question #12

Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?

Response

This question is probably not appropriate for a wide public consultation. With respect, the knowledge and background required to answer the question reasonably is beyond most. And the reflex of many will be to say "yes" with no particular basis for that answer. This then would hardly be an endorsement for PMPRB to proceed to regulatory or legislative changes.

Regulations and Legislation can be considered once pricing, medication access, R&D and innovation/local manufacturing investment implications have been fully researched with stakeholders and relevant ministries. The goal is to ensure Canadians have access to the best innovative medications for optimal health outcomes; and that the equally important impact on the economy is positioned for ongoing strength.
