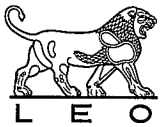

LEO Pharma

April 24, 2009

Dr. Brien G. Benoit
Chairperson
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Dear Dr. Benoit:

I am writing to comment on the latest version of the PMPRB Draft Excessive Price Guidelines, dated March, 2009. This latest draft emerged following a half-year period of review of comments made to the August 2008 version by the PMPRB and clearly demanded a large amount of PMPRB and other stakeholder time and effort to research and develop. The Board is to be congratulated for preparing and distributing a document that presents many changes to the existing guidelines, and further, articulates the rationale behind some of the more significant or contentious changes. The new guidelines have indeed clarified some issues from the previous draft, and have offered processes and procedures to deal with some of the areas of contention that various stakeholders had pointed out. The new guidelines also include some processes and procedures that warrant further comments and consideration. Given the number and intricacy of changes proposed in the new March 2009 guidelines, the 2 -3 month time period allocated for stakeholder review, then collecting, reviewing, discussing and dealing with stakeholder comments, then producing and finally implementing a final version, seems very short.

This latest draft comes at a challenging time in the pharmaceutical industry, marked by company mergers, downsizing and the migration of some skilled activities to non-western countries. Over the past 15 years, drug development has significantly escalated in its complexity. The content of initial regulatory filings has increased dramatically in terms of the sheer volume, the content diversity, the number of patients enrolled in clinical trial programs, and the variety and number of studies (safety / efficacy / pharmacokinetic / pharmacodynamic etc.) needed to gain initial approval.

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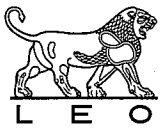
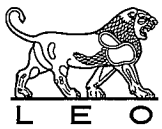


Additionally, in Canada through the Progressive Licensing Framework model, and in other countries through related models, regulatory initiatives are being put into place that will require manufacturers to augment the already ongoing post-marketing gathering of product knowledge through additional structured studies. The standards and demands of warehousing and distribution systems are higher, involving more frequent monitoring, and tighter, cooler temperature control of products at all times during its movement from manufacturer to patient. All of the above contribute to higher costs of bringing new drug products to market, keeping them on the market, and distributing the drug product to patients. Added to this specific additional work, general increases in the cost of living make expenses rise even-higher.

The annual reports of the PMPRB have consistently reported that during this challenging time of drug development, prices of drugs in Canada have remained stable at a mid-range level compared to prices in other countries, and that there is a very high degree of compliance with existing pricing policy. The reports recognize that increasing utilization of medicines, rather than increases in the prices of medicines, is the biggest factor driving increased spending on pharmaceuticals. Thus the rational for making the significant changes proposed in the guidelines, in the process introducing a level of pricing control not seen in any other industry sector, still remains unclear. The doubling of operating budgets for the price review agency over the past few years, with further increases in that budget anticipated in the near future, are at odds with the trends for the pricing of medicines in Canada.

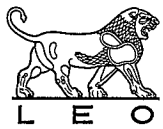
The pharmaceutical industry is an integral part of the health care system. It provides an important service to the system, as do hospitals, laboratories, pharmacies etc. Changes to drug pricing policy must balance the need to allow a healthy, innovative pharmaceutical industry in Canada to co-exist with healthy other components of the same health system. The onus is on the PMPRB to recognize the balancing component of their price management responsibilities. Failure to do so in either direction will have significantly negative consequences in the long run for patients. Instead of protecting consumer rights, terminology which has crept into the stated mandate of the PMPRB, the Board should rather think in terms of protecting patient rights. This demands a dual-focus, long term view accounting both for rights associated with reasonable access to existing medicines today, and the reasonable expectation of newer, better medicines tomorrow. Clearly, policy changes must thus avoid being "punitive" lest they interfere with the ability to achieve the latter.



Pricing policies should be clear and predictable in their ramifications, thereby allowing companies to move forward with a feeling of confidence in their business projections, and requiring a minimum of effort, resources and expense to adjudicate and enforce by the pricing agency. They must recognize ongoing increases in drug development costs through pricing models that allow for updating of prices of reference comparator products, particularly in situations when such prices have not kept pace with inflation. They must allow prices of drug products to take into account realized savings in other health care cost silos.

While the latest guideline draft provides clearer direction on a number of initiatives than the previous version, the attachment notes specific areas wherein the guidelines could be further considered to make them more clearly meet their objectives and performance criteria. In particular, some of the proposed policies of price adjustments can be seen as punitive. It is hoped that further stakeholder consultation can resolve these issues, as opposed to a further escalation of the incidence of combative hearings.

BR
Paul Kidson
VP Medical Affairs
LEO Pharma Inc
Thornhill Ontario
CANADA



Draft Revised Excessive Price guidelines
for comments by April 27, 2009

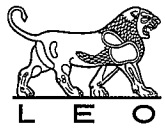
I) Board's rational for its Position on the Proposed Revisions to the Compendium on Policies, Guidelines and Procedures

Page ii, paragraphs 2-5
The Board has taken a full page to justify the need to change the name of some terminology, in particular that relating to introductory maximum price limits. The new term "Maximum Average Potential Price (MAPP) replaces the previous "Maximum Non-Excessive Price" (MNE) terminology. It is true that the PMPRB monitors average prices. The Board states that the terminology change is consistent with the fact that within a given market, some price variation can exist, indeed, "is to be expected", thus making the name change very relevant. However, the new review process, which will expand pricing monitoring across many different markets that overlap each other in a matrix-like fashion, will markedly reduce any price variance possible, making the terminology exercise of little relevance.

Page iii, Publications of the CPI-Inflated Maximum Average Potential Price
The Board states it is prepared to consider acting on such a proposal, and is seeking further comments. This idea deserves Board support and action. Given that a benchmark introductory price is set when a drug first comes to market, and each year the PMPRB agrees that price increases are appropriate up to a defined level, this will provide increased transparency as to what level prices could be if all Board approved price increases were applied by manufacturers.

Even in the absence of applying such an increase to their products price, manufacturers bear the increased cost of living expenses involved in having the product on the market. In not taking advantage of an approved price increase (or giving some other type of discount), the manufacturer was temporarily supplying medicine to patients at prices (further) below which the PMPRB had ruled were not excessive. This surely must be looked upon as a good thing by the PMPRB and the health care system in general. Therefore, when a temporary price discount ends, the proposed policy of not allowing the manufacturer to "reclaim" any unused, otherwise approved price increases, seems punitive in nature.

Similarly, when also looking at the maximum price of newly developed drugs, the proposed policy also appears punitive. The price of comparator products within a reference class of medications cannot be adjusted to include approved levels of price increases that the PMPRB approved over the benchmark price if they were not taken advantage of. The cost of living increases were borne by the manufacturer during the new drug development time.



Page vi, International Therapeutic Class Comparison (ITCC) Test
See also Page 21, Section 5.1, and page 35, Schedule 7
The Board has provided its rationale for making a significant deviation from the proposals of its working group in defining the process for this test. Given that all parties agree that this should not be a first line test, the decision to not make the highest price of medicines in comparator countries the benchmark for comparison (as in the analogous domestic TCC test) is difficult to follow.

Not only does the Board propose to use the median price of drugs in an ITCC comparator range, it also proposes to include generic products in the mix of drugs if they are "relevant and appropriate" – terms that are not defined or explained. The verbal teleconference comment from the PMPRB that industry/stakeholders should be familiar with the inclusion of generics in Therapeutic Class Comparisons from application of the domestic TCC test is also hard to understand. In the domestic TCC test, the *highest* priced component defines the relevant maximum pricing level, so inclusion of generics in this test is of no consequence. Unfortunately, this proposed policy again is punitive in nature.

Page ix, Recognizing Benefits (DIP Methodology)
The inclusion of a process to allow manufacturers to regain *some* amount of lost price increase in the situation of a benefit being offered to clients is reasonable. However, similar to the situation described immediately above, the lack of the ability of the manufacturer to claim the otherwise approved pricing increases foregone when patients were being offered medicines at a special rate is inconsistent with the realities of ongoing cost of living increases. The policy is analogous to a clothing manufacturer offering reduced prices in December and January, but when the sale ends, not being able to increase its prices to a level it would have if the sale had not occurred. Again, this proposed policy in punitive in nature.

L E O

II) Compendium of Policies, Guidelines and Procedures, March 2009

Page 20, Sections 3.2 and 3.3
Policy in these 2 sections relates to comments on Page ix, discussed above. The fact that the PMPRB recognizes that termination of benefits and sales mix changes as "special" circumstances, and provides special considerations in future price adjustments is appropriate. However, limiting the considerations by preventing a manufacturer from applying otherwise approved price increases (in the absence of the manufacturer offering the benefits to patients) is not appropriate.

Page 20, Section 3.6
The wording in this section suggests that price review should be expected to occur in up to 39 different markets ("class of customer in a province/territory"). The remainder of the document talks about review in 16 different markets. This needs clarification.

Page 27, Schedule 2
For clarity, given that the chart has discrete, defined rows of information and columns of information, the make-up of a "Class" should be clearly defined (e.g., is it all products under each individual heading in a highlighted row? If so, the first highlighted row would contain 3 classes – Topical, Nasal/Pulmonary and Oral Solid).

Page 33, Schedule 5 - Median International Price Comparison Test
Section 1.3a
This section speaks to pricing test applied to Breakthrough Medicines at a time when Canadian patients are amongst the first in the world to receive the benefits of the medicine. The pricing policy as stated is punitive.

The policy states that if, after a defined period of time when the Canadian price is re-compared to the international pricing level because of initially insufficient numbers of countries receiving the benefit of the medication for pricing purposes, the price can only be adjusted down or stay the same. There is no provision, given the situation where such a review revealed that Canada's price was below the international median, to adjust the price upwards. The very possible result of this is that because of a punitive pricing policy, Canadian patients should not expect to be among the first in the world to receive new medicines.

The matter should be resolved by revising the policy such that it describes two different scenarios:

1. if the median price is found to be higher than the present Canadian price upon re-review, the maximum Canadian price should be revised up to the median international price.
2. if the median price is found to be lower than the present Canadian price upon re-review, then the existing policy wording can apply

Page 34, Schedule 6 – Highest International Price Comparison Test
Section 1.2
For clarity, the last line of this section should presumably state that the reference group of medication includes only those drugs used to treat the same indication as the product in question.

Section 3.1, Bullet points 1 and 3
This section highlights events occurring that are "beyond the control of the patentee", and provides special redress procedures in the situation that the described scenarios result in the Canadian prices becoming the highest in the world.

The punitive nature of the policy is that, in particular with the situation of currency exchange rate fluctuation, it is quite possible that at some point in time following Canadian currency gaining value against a reference level, further changes could again occur, putting existing Canadian prices "back within the guidelines". However, there is no procedure to recognize this possibility and allow the Canadian benchmark price to be adjusted upwards to "where it was". In fulfilling the balancing demands of their role, PMPRB policies must make reasonable provisions to allow such changes. In the absence, the policy is truly punitive in nature.

Changes in exchange rates, and the removal of a higher priced drug in another international market with the continued availability of the medicine for Canadian patients on the Canadian market should never drive a medicine into a position of being considered excessively priced in Canada.