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Pfizer Canada Inc.

February 28, 2008

Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
P.O. Box L40, Standard Life Centre
333 Laurier Avenue West, 14th floor
Ottawa, Ontario
K1P 1C1

Dear Ms. Dupont:

Please see in the attached Pfizer Canada's preliminary views on the Patented Medicine Prices Review Board (PMPRB) Discussion Paper *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*, issued by the PMPRB in February 2008. Given the very short time for response, and as suggested by the Executive Director of the Board, Pfizer will follow up with more detailed comments at a later date. The attached therefore sets out a high level response to the proposals and options in the Discussion Paper. Pfizer appreciates the opportunity to comment and looks forward to remaining very active, as usual, in later phases of the consultation.

In reviewing this submission, please note that the Pfizer Canada remarks should be viewed as a supplement to the input provided by Canada's Research-Based Pharmaceutical Companies (Rx&D) of which Pfizer Canada Inc. is a member. This submission is intended to support and expand on those ideas in a manner reflecting the experience of an organization that is required to comply operationally with the Board's guidelines. Pfizer Canada has approximately 150 DINs that fall under the jurisdiction of the PMPRB, which makes it one of the most, if not the most exposed patentee with regard to any changes to the regulations or guidelines.

Although outside the context of this Discussion Paper, we would like to express our views on another issue that we have raised repeatedly over the past years regarding patented drugs that are subject to direct generic competition (i.e. same molecule). These multisource patented drugs represent a heavy workload for the PMPRB and the patentee, given that sales in general are relatively small. The formal price reviews to which they are submitted are therefore an inefficient use of resources. In Pfizer's opinion, the Patented Medicines Regulations should be amended to exclude these drugs from the PMPRB mandate. It is not uncommon for such drugs to be at the origin of significant differences in average prices among different classes of trade and/or markets due in particular to competitive hospital tendering. We therefore suggest that the Board includes a discussion of this issue in future consultations.

Thank you again for the opportunity to comment on these important questions. Please do not hesitate to contact me for further clarification or perspective regarding the above.

Yours sincerely,

Nicolas Gagnon

Nicolas Gagnon
Chef à l'établissement des prix
Pfizer Canada Inc.

SUBMISSION TO:

PATENTED MEDICINE PRICES REVIEW BOARD

ON ITS

DISCUSSION PAPER OF JANUARY 31, 2008

"Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines"

by

PFIZER CANADA INC.

February 28, 2008

PATENTED MEDICINE PRICES REVIEW BOARD – DISCUSSION PAPER, JANUARY 31, 2008

SUBMISSION BY PFIZER CANADA INC.

1. "Any Market" Price Review

The Board is concerned that, in a scenario where some markets would be able to negotiate price concessions, the overall national average transaction price (ATP) would possibly remain within guidelines while some provinces/territories and/or classes of customers might pay prices over the maximum non-excessive price (MNEP). During the consultation process, stakeholders maintained the view that "any market" price reviews should be conducted only on a case by case basis. While the Board agreed with this suggestion in its *Stakeholder Communiqué* of May 31, 2007, it now seeks feedback on four proposed circumstances where it would conduct such reviews:

- *Proposal 1 – At introduction*

Pfizer strongly opposes this proposal. Not only does it introduce a formal price review at the level of "any market" contrary to the Board's previous agreement to conduct such reviews on a case by case basis only, but this also becomes a major disincentive with regard to any patient support program. This is a "silo proposal" from the PMPRB that has major ramifications on any other proposed changes to regulations and/or guidelines in addition to creating a significant additional burden on patentees.

In addition, it can be claimed that there is no need for imposing such an additional burden on patentees. Indeed, in the vast majority of cases manufacturers establish one national introductory price that is based on PMPRB guidelines and that is therefore set at or below the MNEP. If there is any "between markets" discrepancy, this means that some markets will actually pay a price below the MNEP rather than above. In rare circumstances where the opposite occurs, current PMPRB guidelines allow for the launch of an investigation following a substantiated complaint and on a case by case basis.

- *Proposals 2 – "Any market" price review when the national ATP appears to exceed the MNEP; and 3 – "Any market" price review in cases of a Voluntary Compliance Undertaking (VCU) or Board order.*

These proposals are equally unacceptable:

- The Board's intent and the process to be followed are not clear
  1. Is it the intent to launch an "any market" in depth analysis / investigation at the first sign that the national ATP may have become excessive? Is the purpose rather to do so when the national ATP reaches one of the current criteria for commencing an investigation?
  2. A corollary to such "any market" investigation is that the Board would conclude to excessive pricing in at least one market (province or territory) and/or one customer class. Would the Board then impose an order or penalties specific to that market while ignoring the fact that other markets / classes of trade are enjoying prices below the MNEP? Would the Board somehow "reward" the patentee in regard to the latter markets?
- Such proposals would impose an immense administrative burden on both the Board and the patentee with regard to the constant monitoring of prices in as many as 56 markets (13 provinces/territories X 4 classes of trade).
- It would become next to impossible to monitor drugs that derive most of their revenues from the hospital market due to the highly competitive tendering processes in that market.

- *Proposal 4 – Any substantiated complaint of apparent excessive prices in any market*

This is comparable to the current third criterion for commencing an investigation ("*Complaints with significance evidence*").

2. Re-Setting the MNE Price

The Board guidelines currently stipulate that it may be appropriate to re-set the benchmark MNEP in two situations: at NOC when a drug is sold as an Investigational New Drug or under a Special Access Program, or when a new drug is sold in less than 5 reference countries. The Board is now proposing to further define / clarify its regulations and/or guidelines by taking into account a wide range of situations in which it might be appropriate to re-bench a patented drug, however by doing so it is impossible for the Board to consider all situations that may emerge with any given product.

It is therefore suggested to leave the current guidelines unchanged and address any peculiar patentee's situation on a case by case basis, on its own merits, by encouraging patentees to consult with the Staff of the PMPRB when in doubt.

- *Cost of Making and Marketing a Drug*

  The Board's suggestion of re-benching a patented drug when the MNEP can be shown to not cover the cost of making and marketing the drug raises a number of issues. To name but a few:

  - What exactly makes up the cost of "making and marketing" a drug?
  - If an existing drug is re-benched numerous years after its launch, re-performing the original price test as proposed by the Board would unlikely take into account the CPI growth over the years (due to more than a decade long reimbursed price freeze policies imposed by provincial drug programs).

- *Insufficient scientific evidence to support categorization with confidence at launch / new evidence that warrants re-categorization*

  Given the work in progress of the Working Groups established by the Board to review its categorization process (which is summarized in another part of the Discussion Paper) and the Board's track record of very rarely granting a substantial improvement categorization, this proposal could result in further delaying the categorization process in numerous occasions. This would translate into further commercial uncertainty for the patentee, not to mention the possibility of a significant increase in workload for the Human Drug Advisory Panel and the Staff of the PMPRB. It should also be said that the Patent Act makes no reference to therapeutic improvement and how to define it, and therefore provides no basis for re-benching a patented drug in this regard. We therefore respectfully suggest that it is outside the Board's mandate to consider re-benching as a result of emerging scientific evidence.

  Overall, Pfizer considers that the two cases described in the current guidelines where the MNEP of an existing drug can be revisited are appropriate, and that re-benching in any other situations should be considered exclusively at the request of the patentee. Again, it seems appropriate to encourage the patentee to consult on an as needed basis rather than "making rules for the exceptions".

- *International Median Based Pricing*

  While the current rules in this regard are rather arbitrary, the PMPRB proposed approaches remain as arbitrary. Overall, there seems to be no value in making any changes, neither for the PMPRB nor for the patentee.

3. Federal Court Decision in the case of Leo Pharma

In its Discussion Paper, the Board describes a number of options in order to address its concerns in relation to the Federal Court of Canada decision in the case of Leo Pharma. Pfizer is supportive of Regulation and/or Guideline changes, if and where necessary, that would allow for the implementation of initiatives that in the end will benefit Canadian patients. In this regard, the Board's regulatory Option 2 *Amend the Regulations to exempt patentees from the requirement to report benefits (payments) provided to third-party payers (F/P/T drug plans and potentially private insurers if similar payments are negotiated in the future)* facilitates patient access to new medications and is acceptable to Pfizer. Deleting gifts from the list of benefits required to be included in the ATP calculations is also acceptable.

Pfizer is also supportive of any programs that directly benefit patients such as compassionate use and/or patient assistance programs. A crucial condition must be met however to allow for such initiatives, that is to adapt the Board's guidelines in order to remove the current disincentives to manufacturers. This can only be done by de-linking the MNEP and the ATP calculations, so that any patient benefits included in the ATP will no longer have the effect of reducing the MNEP over prolonged periods of time, if not permanently. The Board's Guidelines Option 2 makes significant progress in this regard, however the proposed provision "*…some constraint on any single year price increase would be appropriate*" completely defeats the purpose and must be eliminated. Indeed, it is conceivable that only modifications in the size/format of the benefits offered from one year to the other, rather than a price increase as such, could increase the ATP beyond a constraint imposed on any single year increase by the PMPRB. In addition, it simply does not make sense logically that if an ATP is deemed non-excessive (within guidelines) in any given year, that the same ATP can be deemed excessive at any time in the future.

As an example, if product A is sold in Canada at 2$ in 1999, and that this price is within guidelines, an average price of 2$ in 2005 for product A should never be deemed excessive, regardless of how the ATP evolved in between the two time points.