Canadian HIV/AIDS Legal Network | Réseau juridique canadien VIH/sida

7 May 2005

Mme. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, 14th Floor
Ottawa, Ontario
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Dear Mme. Dupont:

Re: Submission to PMPRB in response to *Price Increases for Patented Medicines: Discussion Paper*

The Canadian HIV/AIDS Legal Network is pleased to submit herewith material in response to the PMPRB's recent discussion paper on the question of price increases in Canada for patented medicines.

Founded in 1992, the Canadian HIV/AIDS Legal Network is a national non-governmental organization committed to promoting laws and policies that protect and promote the human rights of people living with, or vulnerable to, HIV/AIDS and that facilitate HIV/AIDS prevention, care, treatment and support. We have almost 300 individual and organizational members, within Canada and internationally. The Legal Network is an NGO in Special Consultative Status with the Economic and Social Council of the United Nations and has provided technical assistance to the Joint UN Programme on HIV/AIDS (UNAIDS) with respect to issues of international law (in the realms of intellectual property, trade and human rights) and access to medications such as anti-retroviral drugs used to treat HIV/AIDS.

In 2004, the Legal Network published the extensive report *Controlling Drug Costs for People Living with HIV/AIDS: Federal Regulation of Pharmaceutical Prices in Canada*. Please find enclosed, in both official languages, a copy of that publication as well as a set of accompanying info sheets summarizing the highlights of the report. Intended for multiple audiences and prepared in advance of the PMPRB's discussion paper, the report touches on numerous aspects of the federal legislative and regulatory regime for controlling the price of pharmaceuticals in Canada and puts forward numerous recommendations aimed at improving the current regime.

In particular, we wish to draw your attention to the following proposals and offer the following observations:

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1. **Compulsory licensing as a remedy for excessive pricing:** We recommend that the Patent Act be amended to re-introduce compulsory licensing into Canadian law (beyond the very limited form in which it is currently available) as a potential remedy for excessive pricing by a patentee. Obviously this is a step that must be taken by Parliament, and falls outside the jurisdiction of the PMPRB. However, it would be helpful if the PMPRB were to recommend that this option be added to its regulatory toolbox in order to ensure adequate protection of consumers.

2. **Using "value" of a drug to determine maximum price:** Given the PMPRB's efforts to define the "value" of a drug, we recommend that this also be reflected in the Board's guidelines for setting the maximum non-excessive price for Category 2 new drug products (breakthrough drugs), and not simply Category 3 drugs. If the value of a drug is relevant to regulating its price in the case of "me-too" drugs, then surely the same principle must apply in the case of breakthrough drugs. This is a matter falling within the jurisdiction of the PMPRB.

3. **Lower cap on maximum price of "me-too" drugs:** We recommend a change to the Excessive Price Guidelines to better control the introductory price of Category 3 drugs with a more effective (and lower) cap on the maximum permissible price. This is a matter within the purview of the PMPRB. Category 3 drugs account for the largest proportion of total sales of patented drugs, and a significant number of drugs in this category continue to be priced above media international levels. Better controlling prices of drugs in this category (which, by definition, offer moderate, little or no therapeutic advantage over existing drugs) would help achieve significant savings for consumers and payors. We recommend two options here. The first is to limit the introductory price of a Category 3 new drug to the *lower* of either the median (or even the lowest) international price charged in the comparator countries or the highest price in Canada among all therapeutically comparable products. The second option would be to cap the introductory price of Category 3 new drugs to either the media or the average of Canadian prices for all drugs in the same therapeutic class.

4. **Limiting price increases on existing drugs:** We recommend that the PMPRB review the appropriateness of using an index based on retail price increases to limit the increase in ex-factory prices charged by manufacturers of patented medicines. Allowing a manufacturer's factory-gate price to increase at the rate of *retail* prices potentially "frontloads" an increase into the base price, which is then further marked up along the wholesaling and retailing chain, compounding over time the inflation of final drug prices. Changing the way in which the CPI is used by the Board in its assessment of permissible pricing by patentees is entirely within the Board's purview.

5. **Ensuring a better correlation between prices and R&D spending:** We are concerned that pharmaceutical patentees have not been living up to their end of the bargain, reflected in the Patent Act amendments of the late 1980s and early 1990s, of increasing their Canadian R&D in exchange for enhanced patent protection. We therefore recommend that the PMPRB identify options for further amendments to the Patent Act, the Patented Medicines Regulations and/or the Board's own Excessive Price Guidelines to produce a closer correlation between overall Canadian price levels for patented medicines and levels of spending in Canada by patentees on pharmaceutical R&D.

6. **Change the set of countries used for international price comparisons:** We recommend that the PMPRB consider, through a process of public consultation including consumer

representatives, changing the set of countries used for the purposes of international price comparisons. In particular, we note that the United States is consistently the major outlier, among the seven countries currently used for such comparisons – it is the country with little or no form of direct price control, unlike all the others, and not surprisingly, regularly reports significantly higher average prices on patented pharmaceuticals. There seems to be little justification for including the US among the comparator countries for Canada's purposes when both its health care system and its approach to regulating pharmaceutical prices is so different from Canada or the international norm, and its inclusion artificially skews upward the maximum "non-excessive" price permitted to a patentee in Canada. We understand that the objective of the PMPRB's current is to identify ways of ensuring ongoing price stability in Canada. If so, then tying our price control system to a country that has few such mechanisms for ensuring stability for its own consumers, and is highly unlikely to introduce such mechanisms, becomes even more counter-intuitive and counter-productive.

7. **"Cost plus reasonable profit" approach to pricing:** We recommend that the PMPRB revise its Excessive Price Guidelines such that maximum non-excessive prices allowed to patentees bear a reasonable relationship to the costs of their development and manufacture, plus a "reasonable" profit margin beyond those costs.

8. **Interim or conditional pricing of new drugs:** Canada's price control system would benefit from a mechanism for interim or conditional pricing of a new patented medicine when introduced to the Canadian market, with the maximum non-excessive price reviewed at appropriate periods to take into account new evidence regarding its "value" (i.e., its therapeutic merit and its merit relative to comparator medicines). We recommend that the PMPRB examine options that would give it this jurisdiction and put forward proposals to the government for the necessary amendments to statute or regulations.

9. **Regulating prices of generic medicines:** The PMPRB should propose to the government that it enact a national legislative scheme to prevent excessive pricing of all medicines after patent expiry, including products made by generic manufacturers.

10. **Enhance reporting requirements:** The PMPRB has repeatedly expressed its concerns about the failure of a significant number of patentees to meet, in a timely fashion, their statutory obligations to report on sales and R&D expenditures. The Board should, therefore, put forward proposals for Patent Act amendments that would enhance penalties for non-reporting. It should also recommend legislative amendments that would require patentees to report annually on their promotional activities and spending on each type of such promotion. Finally, it should recommend that manufacturers of non-patented medicines be legislatively required to report on sales and R&D expenditures, to generate fuller picture of the activities and performance of the entire pharmaceutical industry in Canada.

11. **Strengthen R&D spending requirements:** As noted above, patentees as a group do not appear to be meeting their previously stated commitments of R&D spending in Canada in exchange for enhanced patent protection. The PMPRB should recommend to the government that it amend the Patent Act to impose legally binding requirements for R&D spending in Canada, with levies on those who fail to meet these standards generating monies that can be dedicated to publicly funding research into "neglected diseases", in particular those prevalent in developing countries.

These recommendations are discussed in more detail in the enclosed report, which we hope will be useful to the PMPRB in your ongoing discussions of ways to improve Canada's current system for preventing excessive pricing of pharmaceuticals.

With respect to the specific questions set out in the Board's discussion paper, we offer the following comments:

- We recommend that the Board move to a system that requires prior approval of any proposed price increase by a patentee.

- We have noted above our proposal for a conditional or interim pricing system upon the introduction of a new drug product, with subsequent periodic reviews in light of emerging evidence about a drug's therapeutic value, which should be one criterion used in the event a patentee seeks to justify a price increase.

- We have noted above that the CPI, as a retail price index, is not necessarily appropriate for use in regulating manufacturers' ex-factory prices. While the CPI is, by statute, a factor to be considered by the PMPRB, it is necessary to perhaps adjust either the CPI figure itself or how it is applied, in order to avoid artificially inflating the permissible level of price increases by manufacturers of patented medicines.

We look forward to further opportunities to provide input to the Board as you identify options for improving Canada's current system for preventing excessive pricing of pharmaceuticals. We are concerned, as are many consumers/patients and health groups, at the ongoing pressure which is being brought to bear, in particular by the patented pharmaceutical industry and the United States government, to weaken a regulatory regime that has served Canada and Canadians well even if it can be further improved. In these circumstances, it is also critical that the PMPRB, especially at a time of turnover in the leadership and management of the Board, will continue to see its mandate as ensuring consumer protection and ensuring that Canadian policy on pharmaceutical issues is informed by the public interest and by evidence, rather than industry pressure.

Sincerely,

Richard Elliott
Director, Legal Research & Policy

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