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

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Dear Dr. Benoit,

Cancer Care Nova Scotia appreciates the opportunity to respond to the Discussion Paper on Drug Price Increases. This response was prepared with the significant input of Larry Broadfield, Cancer Care Nova Scotia's Manager of Systemic Therapy.

The rapid increase in the cost of drugs to treat cancer or ameliorate cancer and its symptoms is of great concern to our organization. Where new agents in the 1990's often cost a few thousand dollars per treated patient, more recent drugs cost tens of thousands of dollars per patient. This dramatic increase in drug costs is well beyond inflationary growth and beyond traditional funding models for publicly funded health care. The consequence is a challenging environment of balancing quality patient care with fiscal imperatives.

The significant cost increases for drugs in general, and cancer drugs in particular, has placed the public system into an increasingly difficult position. New drugs, with significant but modest improvements in patient outcomes (such as length of survival), are priced well beyond the traditional benchmark of what the public purse has covered to date, and continue to escalate. For instance, Avastin was recently reviewed by the Nova Scotia's Department of Health's Cancer Systemic Therapy Policy Committee. With Avastin being evaluated as costing > $150,000 per life year gained for treatment of advanced colorectal cancer (the traditional maximum is about $50,000). This was the price negotiated with the PMPRB. In the US, this same drug was recently approved for use in advanced breast and lung cancers, at twice the dose, and twice the price for a comparable outcome of survival improvement measured in a very few months. There are other similar examples of new cancer drugs on the market, or imminent to the Canadian market.

It would appear to us that the Excessive Price Guidelines developed in the 1980's does not reflect the changing pharmaceutical market of this decade. While we claim no expertise in the costs incurred for drug development by manufacturers, we note that there has been no significant increase in clinical research efforts locally or nationally that could explain the magnitude of drug pricing increases, especially for the more common cancers (e.g. breast, colorectal, lung, prostate cancers). We would advocate for changes that attempt to maintain a healthy balance between reasonable industry pricing and the ongoing challenges of managing the public health care system within a sustainable growth rate.

To respond to the specific questions posed in the Discussion Paper:

Issue 1- *Is the current approach to the categorization of new patented medicines appropriate?*

- The categories appear appropriate, but definitions are unclear. In the area of cancer, which is comprised of thousands of specific types, stages and disease characteristics, it is hard to identify the difference between significant and moderate therapeutic improvement. In some circumstances, the improvement is measured as overall survival, in other circumstances as disease free survival, and sometimes in terms of symptom improvement. Often, improvement is measured as a response rate, yet this is only relevant if the response is a surrogate measure for better survival or quality of life.
- There also needs to be clarity of accountability for the decision around whether a new drug offers therapeutic improvement, and to what degree. Explicit criteria should be developed to rate the degree of improvement, and made publicly available for open accountability. Given the stakes at hand, it might be reasonable to enlist independent experts in the clinical area (in this case, oncologists), health care administrators, bioethicists and other appropriate representatives in the assessment of each new submission deemed to be a 'therapeutic improvement'.

Issue 2- *Is the current approach used to review the introductory prices of new patented medicines appropriate?*

- Given that the comparator countries are polled for a median unit price (the IPC), we wonder if any of the countries' drug policies mirror those in Canada? In particular, there needs to be a re-assessment of comparator countries to determine that some (preferably most) have a similar mix of public and private funding for drugs. In Canada, where almost all drugs administered in health care facilities (e.g. hospitals, ambulatory clinics) are funded through the public purse, it would be inequitable to compare drug prices only with countries where most or all of the drug costs are paid by private insurance. Public health insurance necessarily covers all members of society and cannot screen our high risk patients like private insurance can. Thus, the public system is under greater pressure to control costs. Drug costs for comparable health care systems should be factored in to the IPC. Arguably, comparison costs for predominantly private drug insurance countries should be excluded for hospital-based drug product price comparisons (for a more equitable 'like-to-like' comparison).
- It is hard to identify "comparable medicines" in cancer care, using traditional models. Instead of comparing, for instance, two different drugs used to treat advanced breast cancer, we should consider a comparison of medicines used to treat a variety of cancers with similar outcomes (such as advanced prostate cancer or advanced colorectal cancer, where survival outcomes appear similar). In addition, we rarely use a single drug for treatment, so comparisons should be made with common multi-drug regimens. These regimens are categorized by several Canadian cancer agencies (e.g. Cancer Care Nova Scotia, Cancer Care Ontario, British Columbia Cancer Agency), several with comparable drug cost models incorporated. Further, we need to be clear how the new drug will be used- as mono-therapy, in combination with other drugs, as sequential treatment, or other models to understand the actual price comparisons. The PMPRB could use clinical experts to outline the current and predicted usage of any new drug (based on clinical research underway) to help model usage and costs. This would greatly assist provincial decision-making groups to understand drug costs and to formulate public funding strategies.

Issue 3- *Should the Board's Guidelines address the direction in the Patent Act to consider "any market"?*

- The Board needs to be aware of the changing prescription drug marketplace across Canada in consideration of this issue. Although only 2% of Canadians do not have any prescription insurance (for drugs acquired through community pharmacies), ALL of these citizens live in Atlantic Canada (report by the Fraser Group). Nationally, this is not an overwhelming problem, but in Atlantic Canada, this translates to 25% of all Atlantic Canadians who have no prescription insurance. Further, when one factors in models for under-insurance (people who cannot afford their co-payments of 10-20% of the total cost), up to 70% of Atlantic Canadians face financial hardship for prescriptions costing in the range of $1000. There is no mechanism in these 4 provinces to ameliorate 'catastrophic' drug costs (out of pocket costs exceeding 3-4% gross annual income). This would qualify as a specific 'market' within Canada, we believe, and deserves consideration by the Board.
- The hospital sector is another unique market, as described above, and ought not to be combined with retail pharmacy when developing price comparisons or making pricing decisions. While hospitals generally acquire drugs at slightly below the MNE (through organized group purchasing mechanisms), they also face different pressures in the public health care system.
- One other point of concern to the health care system is the lack of price controls for drugs acquired through the Special Access Program. Although the SAP is intended to be used for individual cases, recent activities have subverted the intent and utilized the SAP as a routine mechanism to acquire 'standard-of-care' oncology drugs, in particular Oxaliplatin and Thalidomide. With no mandate to undergo price review, the single-source manufacturers have charged Canadian health care institutions any price they chose, generally the same as charged in the US. The Board should consider future mechanisms to consider price reviews for SAP drugs in certain circumstances, to prevent this technical loophole in future.

In conclusion, the PMPRB plays a crucial role, but does not appear to have any degree of accountability or communication with the health care professionals, clinical specialists, or drug-funding decision-making bodies. In recent years, there has been an increasing divide between prices approved by PMPRB and the ability of the public health care system to reasonably absorb costs of new drugs. This division is particularly of concern for several cancer care drugs recently released on the Canadian market or anticipated in the foreseeable future. We would like to see a process in which the concerns of clinicians and health care funding agencies are considered in the pricing control decisions, along with those of industry. This model would be more robust and sensitive to continuing market changes as we strive to sustain the public health care system.

Sincerely,

T. M. Underhill

Theresa Marie Underhill, M.Ed.,MHSA
Chief Operating Officer
Cancer Care Nova Scotia

cc: Larry Broadfield

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