Canadian Arthritis Patient Alliance

Working with The Arthritis Society to make a difference in the lives of people with arthritis

August 24, 2006

To: Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
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Re: Consultations on the Patented Medicine Prices Review Board's Excessive Price Guidelines

The Canadian Arthritis Patient Alliance (CAPA) thanks Dr. Brien Benoit and the Patented Medicine Prices Review Board for the invitation to take part in the consultation process on introductory patented drug price review.

The Canadian Arthritis Patient Alliance (CAPA) is a national, grass-roots, patient-driven organization of arthritis consumer advocates with members across Canada, all of whom are dedicated to improving the quality of life for people living with arthritis. We are dedicated to improving arthritis care and services, and we believe that the best treatment decisions include real-world information. Ours is first hand experience, and we are pleased to be able to contribute our objective knowledge to this consultation.

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

Question 1: Are the new patented drug categories and their definitions appropriate?

Categories 1 and 2 are fine and the definitions are appropriate. However, in considering Category 3 it's important to recognize that people living with serious chronic illness typically take a variety of medications concurrently, and it's common that therapeutic interventions that work well for one patient with the same diagnosis may not work well – or at all – for another. 'Me too' drugs are therefore necessary, for when one 'fails' another can be tried. Moreover, it is the effect on the patient that determines whether or not the new product provides 'moderate' or 'little or no' improvement over other similar drugs. There is no other reliable measure. Without an efficient, patient-centered, post market surveillance program that includes monitoring of the life cycle of the drug, this is not possible.

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Question 2: Is it important to distinguish a medicine that offers 'moderate therapeutic improvement' from a medicine that provides 'little or no therapeutic improvement?' If yes, why is it important? If not, why not?

Distinguishing between 'moderate' and 'little or no' improvement is undoubtedly important to industry, as even a moderate improvement might seem to excuse higher prices as well as greater advertising and product detailing efforts. But the fact remains that individual responses to medications determine whether any symptom improvements is the result of a particular medication, or that medication in combination with other drugs. Using NSAIDs as an example, two different drugs considered by medical professionals to be of equal therapeutic benefit in controlling inflammation and pain, may have quite different levels of effectiveness in individual patients. Determination of the degree of effectiveness (i.e. 'Little or no' or 'moderate' therapeutic improvement) of a new drug would seem to be largely based on the reported results of a multi-centre clinical trial - possibly against placebo only, ATC Classification System, and a marketing exercise – unless such categorization is based on extensive post market surveillance from which reliable information may be drawn.

Question 3: If the answer to question 2 is yes, on what basis would a new medicine that offers 'moderate therapeutic improvement' be distinguished from a new medicine that provides 'little or no therapeutic improvement?'

People in the real world take medications and most of them don't meet the same strict inclusion/exclusion requirements of the clinical trial – possibly against placebo – that provided the performance information on the new drug. All that can be said is that the trial intervention was better than placebo. Head to head comparisons are required. Post market surveillance over the life cycle of a drug is required to inform patient safety issues as well as drug efficacy. Best evidence treatment information is required. In any event, when does 'little improvement' become 'moderate' improvement? The line between the two is undoubtedly very fine, and ripe for dispute.

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

Question 1: Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not?

Current Category 3 pricing allows 'me too' drugs to enter the market at high price points. These medications are alternatives to existing drugs, they are not breakthrough drugs. The usual arguments about high R&D costs don't hold water. Companies know well that their product will be competing with other therapeutically similar medications. These products are intended to be profit generators in spite of not being innovative. Introductory pricing of such therapeutically comparable products should be reflective of generic pricing of similar products, and production and marketing costs of generic companies should also be used as a reference. For a full 25% of actual 2004 Category 3 prices to be higher than the Median IPC, is alarming (Fig.4 in PMPRB guide.) Clearly, the TCC rule doesn't work well in this situation when a new 'me too' needs only to *not* exceed the highest price of Canadian therapeutically comparable drugs. And what patients pay is higher still.

Question 2: If you think that medicines that offer 'moderate therapeutic improvement' should be distinguished from medicines that provide 'little or no therapeutic improvement' what would the appropriate new price test be?

As previously suggested, it isn't realistic to try to accurately differentiate between these categories in most cases. Unless such delineation can be accurately determined in *all* cases, it ought not be done. Advertising and detailing notwithstanding, market conditions are on the side of a drug that actually is a moderate therapeutic improvement.

Question 3: Do you have any suggestions as to principles or criteria that should be used in determining how to identify 'comparable medicines' for the purpose of inclusion in the above price tests?

As previously indicated, the only way to determine this is through head to head clinical trials, and a worthy, patient-centered, post market surveillance program over the life cycle of the medication.

Question 4: Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85(1) of the *Patent Act* states the Board should take into consideration 'the prices of other comparable medicines in other countries'. Should the guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?

By using the IPC test Canada is taking into consideration pricing in other countries. The implication of the question appears to be that these may not be representative countries. We could toss out the U.S., as their pricing is very different from ours, and replace it with a country with far lower prices, and all we would have accomplished is to shift the numbers a bit. We could increase the number of countries, or reduce the number, but the process would be the same, and the results would benefit those who argued successfully on which countries to remove or add. If the idea of applying tests to pricing is to determine an equitable price that enables a reasonable profit to be made by the manufacturer at the same time that symptoms and diseases are cured or held in check at a reasonable cost – economically and physically - to those using them, then the measures must be those that permit this to occur. They must also reflect the conditions in Canada and of Canadians. If any countries are added or deleted from the list, or if from time to time pricing of a drug in other countries is used as a reference, it must not be done to disproportionately benefit any one party (manufacturer, hospital, wholesaler, patient, etc) but must always consider patient access and need first. This whole business is primarily about equitable access to reasonably priced medicines for Canadians.

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

Question 1: Given the price variation by provinces/territories and classes of customer illustrated in the previous figures, is it appropriate for the board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?

When a patient purchases medication at the pharmacy, he/she doesn't pay the ATP calculated on the base of total revenues from sales for all provinces, territories and classes of customer. The patient pays what the wholesaler charged the pharmacy plus mark ups, dispensing fee and taxes. Whether purchased at a pharmacy or utilizing the drug in a hospital, and no matter where the patient lives across Canada, the patient is the end user. It is what the patient pays that is the concern, and the cost of a medication can affect patient access to medications required. A province-wide ATP is a better determinant of patient cost, and smaller markets should also be spot-checked if there is widely discrepant pricing across the country.

Question 2: If the current ATP calculation is not appropriate, should the board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-case basis, where there is a significant variation in the prices charged?

Such a broad review is a good idea. Review of what different classes of customers are charged in different provinces, and also review on a case-by case basis, will provide better clarity about what end users pay and determination of excessive pricing where it exists.

Sincerely yours,

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