APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

October 11, 2007

Brien G. Benoit, MD
Patented Medicine Prices Review PMPRB
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2007 OCT 15 PM 3:02

Dear Dr. Benoit:

Apotex commends the Patented Medicine Prices Review Board for its foresight in inviting individual companies to comment on policy changes it is contemplating and to seek as much information as possible. Apotex believes it has a unique perspective on the Canadian market which we are more than happy to share with the PMPRB.

Apotex is a Canadian-owned generic manufacturer and is among the world leaders in this market. Apotex has very significant presence in many world markets and is among the largest generic companies in the US market. As a consequence, we believe Apotex is ideally situated to provide important insights into the operation of the North American generic industry and to contribute to the formulation of reasonable pricing regulations.

We have provided our comments in the attached document. Briefly, we can state that the current Guidelines were not designed to deal with the highly competitive generic market and will have an effect that is contrary to the best interests of Canadians. Based on this position and our belief that Board members have recognized these issues, we recommend that any investigations that may be underway concerning generic drug prices be suspended until this consultation process has been completed and the Board determines the best course of action. Undertaking substantive investigative activity into the pricing of generic drugs appears to be a pointless, yet costly, exercise given the chance the Guidelines will be altered.

Based on the history of the legislation and its intent, there should be a balance between new drug development (both brand and generic) and consumer protection. One of the keystones of the original legislation was to ensure the early availability of new medicines in Canada. We would add to this the early availability of generic products should also be included. The consumer protection mandate must, in our view, weigh drug availability ahead of price concerns.

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We hope that these comments and those in the attached document are useful for the Board in its deliberations. We would be pleased to provide further information on any aspect of the generic industry, either here or in the US should that information be useful for the Board.

Yours very truly,

APOTEX INC.

Jack M. Kay
President and C.O.O.

SUBMISSION TO THE PATENTED MEDICINE

PRICES REVIEW BOARD

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FALL 2007 CONSULTATIONS

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Introduction

This submission is pursuant to Dr. Benoit's invitation to Apotex to provide input into the policy formulation process the Patented Medicine Prices Review Board has undertaken.

Apotex supports the CGPA position that the current PMPRB Guidelines are not appropriate for generic drugs. As described in that submission, generic manufacturers must have the flexibility to react to economic and competitive changes. Apotex would like to add to the comments provided by the CGPA as a means of assisting the Board in its deliberations.

Transition Period

The Board has engaged in an extensive consultation period during which it has learned there are serious issues with the current Guidelines and their application to generic products. We believe the Board has recognized the need for Guideline changes and their application which will address the peculiarities of generic product pricing. Despite this, PMPRB staff continues to review generic drug prices under these Guidelines. Staff appear willing to recommend that hearings be held into matters that may well become irrelevant if and when guidelines are introduced that better fit the generic industry. These actions seem to prejudge the Board's deliberations on new policies and Guidelines.

While we appreciate the staff's dedication and sincere efforts, we would like to point out that there is a significant cost to companies in dealing with these reviews. This comes in the form of our staff time, management time and the distraction from developing new drugs for the Canadian market. We assume it has the same impact on PMPRB staff.

As a first step in changing the current situation, Apotex recommends the Board staff be instructed to hold any investigations concerning generic drug prices in abeyance until a decision is reached on what should be done with generic pricing. The damage caused by pursuing investigations on generic prices is irreparable and there is nothing to be gained by the Board.

Legislative Intent and PMPRB Mandate

The Patent Act changes of 1987 and 1991 (Bill C-22 and Bill C-91) had a profound negative impact on Apotex and other generic companies. Needless to say, Apotex followed the legislative debates closely and as a result, has detailed insights into the background and intent of the legislation. This legislation was implemented to increase

R&D in Canada and rebalance intellectual property rights. It was also intended to protect consumers, the most important aspect of which was to ensure new drugs are introduced promptly into Canada. The PMPRB was created to protect consumers from "excessive" prices, not to systematically force prices down to the lowest possible level.

We believe the price regulations are being applied in a way not contemplated by Parliament. This is demonstrated in recent efforts to place regulatory constraints on drugs which are in a highly price competitive environment. The manner in which these price controls are being administered now will have a significant impact on our ability to conduct business in Canada and could result in fewer competitors. This will impose higher regulatory costs on generic manufacturers which will eventually be passed on to consumers.

We strongly suggest the Board carefully balance its mandate between industrial considerations and consumer protection. The concept of consumer protection must weigh the desirability of the availability of new brand and generic drugs and should not be limited to a single focus on pricing.

A Case Study

Setting the price for a new generic product, including establishing the incentives necessary in the market place, is an uncertain business. It is not uncommon to find the introductory price of a new generic product is too high or too low given production costs, competition, government acceptance, pharmacy acceptance and a host of other factors.

Apotex has found in some cases, the initial price of a new DIN of a multisource product has been too low. In one case, it became clear shortly after we began selling this product that its initial price was not sustainable. This required a significant price increase yet even the new list price remained 47% below the brand list price. Under current Guidelines, this product could be subject to a hearing because of the price increase even though it has remained at a fraction of the price allowed under the introductory price test and every provincial drug plan accepted the new, higher price.

This demonstrates there is no incentive to offer the lowest possible initial price since in doing so under the present Guidelines, there is no prospect of increasing it if the manufacturer finds the price to be unsustainable. The rational manufacturer would mitigate this risk by only introducing new generic products at the highest possible price. This is not in the best interest of consumers. In some cases, generic manufacturers may forgo licensing in new generic (patented) products because of potential price restrictions. This too, is contrary to the best interests of consumers.

PMPRB Staff Interpretations

It is quite apparent that the number of hearings and the challenges to drug prices has increased dramatically in the last few years. While Apotex has no information on the cause of the change in the pattern of price enforcement, this trend is very dangerous for

the future of smaller companies and the Canadian industry. It is very expensive to prepare for a hearing and to carry it through. The mere threat of this level of legal action would be sufficient to intimidate smaller companies.

It appears that PMPRB staff is interpreting the Guidelines in a manner which results in the lowest possible price for the product under review rather than a "non-excessive price". This was not the intent of the legislation and we are informed, is a fairly recent trend. Regardless of the cause, this will have a substantial impact on the generic industry. Apotex suggests that the staff and Board consider the full ramifications of hearings and the effects the very rigid interpretations being placed on the Guidelines will have on drug availability and competition. To reiterate, it was the intent of the Patent Act deal with "excessive" prices and was clearly not to impose a regime which requires manufacturers to charge the lowest possible price nor was it to controlling price changes where the prices are not excessive.

Generic Patent Strategy

Apotex has obtained patents in order to be able to gain early entry into the market with lower priced drugs, neither to monopolize the market nor to enhance its pricing power. Brand companies or other international generic raw goods manufacturers often have multiple patents on manufacturing processes etc. that can block competitors or at least substantially increase the risk of facing very costly patent infringement actions. In order to avoid the effects of these patents and permit the early enter into the market, Apotex has had to invent new production processes. It is not enough to invent the new, non-infringing process but it is also necessary to patent them so that competitors cannot patent the new process thus blocking our entry. If Apotex did not have the patents it does hold, we would not be competing with brand companies for some drugs and would not be providing lower prices to Canadians as early as we do.

It is highly questionable public policy for the PMPRB to enforce price regulations on companies which obtain patents so that they can bring lower priced drugs to Canadians. Apotex recommends the Board and staff consider the relevance of the patents that require regulatory filing.

PMPRB Guidelines

The Guidelines are flawed when it comes to regulating generic prices both with respect to introduction prices and price changes. This was well explained in the CGPA submission and we will not reproduce that material here. We would like to emphasis that Apotex operates in a very competitive market sector. In addition to input costs, competitive reality means we may have to increase or decrease purchasing incentives offered to buyers. We are competing with companies that do not have patents. If the Guidelines are enforced as normally interpreted by staff, this will place Apotex at a disadvantage to competitors with no net positive effect on consumers.

Price changes that do not result in the new price exceeding the allowable price determined by the introductory price review tests should not trigger a review by the PMPRB. That would be consistent with a reasonable interpretation of the Patent Act and would remove the major part of the issues faced by the generic industry.

Conclusions

We find it disconcerting that sections of the Patent Act intended to protect against excessive prices is being applied in a way that actually diverts attention away from developing new lower cost generic products and which raise our cost of doing business. The current Guidelines do not permit sufficient price flexibility for generic manufacturers that have prices lower than brand name competitors.

We recommend the following:

Board instructed staff to hold any current investigations in abeyance until the Board makes a decision regarding the Guidelines applicable to generic drugs. Actions taken before revised Guidelines are in place will cause irreparable harm to the companies involved.

The Board's mandate should be a balance between industrial considerations and consumer protection. The introduction of new brand and generic drugs should be a central theme in the mandate.

The Guidelines or as part of the administration of the Guidelines, should consider the extent of price competition existing for the product and differentiate between drugs having patents which create a monopoly and those that do not.

Price fluctuations below the price permitted by the introductory price tests should not be a prima facia case of Guidelines violation. Generic companies must have the flexibility to increase and decrease prices without the threat of regulatory involvement. This includes introducing at a relatively low price and subsequently increasing as well as fluctuations during the patented life of the product.

A simple to administer and effective policy would be to permit price changes as long as the price does not exceed the allowable price established by the introductory price review tests.