Canadian Generic Pharmaceutical Association

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Ms. Sylvie Dupont
Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Dear Ms. Dupont:

On behalf of the Canadian Generic Pharmaceutical Association (CGPA), I am pleased to provide comments on the Discussion Paper for Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines.

The comments contained herein pertain to the application of the Patent Act, the Regulations, the PMPRB Guidelines and various PMPRB administrative policies to patented generic products. These comments have been limited to the issues contained in the Discussion Paper, but do not necessarily follow the sequence found in that document.

Principles

As stated in the January 31, 2008 Discussion Paper (page 8), the government's objective in creating the PMPRB was to "ensure the additional patent protection provided to pharmaceutical patentees stemming from changes in the Act did not translate into excessive prices." The entire thrust of the price review provisions was aimed at the parties which benefited from the modifications (and later elimination) of compulsory licensing of pharmaceuticals (Section 41(4) of the Patent Act in force in 1987).

It is obvious that Canadian generic companies did not and do not enjoy any benefit from the legislative changes and to now have them face significant administrative burdens and price controls is not consistent with government objectives. The CGPA believes the degree of oversight accorded to patented generic drug prices must be moderated given the government's objectives and the realities of the competitive market place.

The PMPRB proposes including reference to "protecting the interests of consumers" in its mandate. Consumers are protected when competition is unhindered. By definition, competition will result in price fluctuations. Regulating patented generics by limiting price fluctuation only hinders

competition. Moreover, this only affects those generic manufacturers that have patents. There are generic manufacturers that have unpatented drugs which are direct competitors of patented generic products. The former are not regulated by the PMPRB. Therefore it is not clear how regulation of price fluctuations of patented generic products protects consumer interests.

A second important consideration in the PMPRB mandate is the fact the legislation was aimed mainly at industrial development. While the focus on consumer protection is laudable, it cannot be the sole focus of the Board. The Board must weigh the impact on the pharmaceutical industry, both generic and brand companies.

CPI Methodology

Under current regulation, the maximum non-excessive price (MNE) in one period is a function of the average transaction price (ATP) in the previous period. The (ATP) cannot normally rise by more than the change in the Consumer Price Index but could fall dramatically as a result of a discount to certain classes of customers (e.g. hospitals), rebates, free goods and other promotional activities. These tend to be of benefit to consumers, and companies should not be dissuaded from doing these things. However, the current CPI-Adjustment Guidelines do just that.

The market for generic products is characterized by sharp and sudden price fluctuations, both up and down. The current methodology is therefore completely unacceptable for price regulation of generic products.

The Discussion Paper suggests that changes may be required to allow the re-benching of benchmark prices; changing the reporting rules and the Regulations; and conducting price reviews at the market level. The CGPA's opinion is that the current restrictive CPI methodology creates an artificial distortion which, once corrected, makes the other suggested changes unnecessary and even harmful to Canadian business.

Possible Changes to the CPI-Adjustment Methodology for Determining the MNE Price

The Board has suggested two options for the CPI Price-Adjustment methodology that it believes would be in the best interests of Canadians. The CPGA is in general agreement with the principles contained in these options, although a few minor refinements to the second option would best serve the interests of both consumers and industry. Our position follows.

Generics are often launched simultaneously as soon as the molecule patent for the brand version of the chemical expires. Therefore, the first period is often characterized by fierce competition and as a result generic prices are significantly discounted starting at launch, in an attempt to capture the highest market share possible. It would not be acceptable to subject generic medicines to a maximum price that was fixed by discounts in the first period, which may not be representative of future pricing. We believe the second of the options described in the Discussion Paper resolves a number of problems. (The establishment of the benchmark price for generic products is described later in this document.)

Generic medicines are copies of the brand medicine and therefore are the same medicine. Therefore, if brand prices are not excessive, generic prices that are lower than the brand prices cannot be excessive, regardless of fluctuations. It would not be appropriate to impose any caps on generic prices as long as these remain below brand prices. The CGPA also notes that provincial governments have a very substantial control over the prices paid for drugs covered by their plans. This will, in itself, moderate some of the fluctuations.

The CGPA recommends that Option 2 of the proposed changes to the CPI methodology be implemented, with the provision that the generic price must be lower than the CPI-Adjusted brand MNE price. There would be no restrictions on the fluctuations of the generic ATP as long as the price remained below that of the equivalent brand.

Regulatory Changes

As noted in the PMPRB Discussion Paper, the options are inter-related. The CGPA believes that the proposed Option 2 CPI-Adjustment methodology removes any need to alter the Regulations. Under the proposed refinement to Option 2, there is no incentive or disincentive for manufacturers to not report all of their sales and rebates since this would not affect either current or future allowable prices.

Categories of Medicines

The Discussion Paper makes no mention of specific Guidelines or treatment of generic products. This is the subject of discussions by a working group. However, the Discussion Paper includes reference to Categories of Medicines and hence it is appropriate for the CGPA to include reference to this important issue in the context of responding to the Discussion Paper.

Generic products should logically be classed as Category 1 Medicines. The rationale follows:

- Generics are by definition and regulatory approval, identical to brand name products. They are therefore the same medicine.

- Generic products are sold in the market as interchangeable to brand name products and are priced below the equivalent products. This means the logical comparison is the Canadian price of the brand versus the Canadian price of the generic equivalent.

- The PMPRB staff and Board have consistently ruled that line extensions of brand products are category 1 new drugs even where there have been substantial clinical differences and even where there have been different manufacturers. A list of examples can easily be prepared if necessary.

- The Guidelines define the same chemical in the same or comparable dosage forms to be Category 1. There is no reference to the manufacturer.

- There is nothing in the legislation to differentiate a medicine based on the manufacturer.

It is therefore reasonable to conclude there is only one possible classification for a generic product and that is as a Category 1 new medicine.

Price Tests

As a Category 1 medicine, the price of generic products must be set versus the price of the equivalent brand product. The price for the brand would be the highest list price on record since the brand medicine's launch adjusted for inflation from the time of its introduction. This sets the MNE for all generic products equivalent to the brand's MNE.

If a certain price was considered not excessive in a previous period, that price cannot be considered excessive in a later period, whether it is a brand or a generic version of the medicine. Therefore, the only possible comparable price to the generic medicine is the higher of the introductory MNE and the selling price of the brand. This ensures that the international comparison is already accounted for.

International Prices

Given the structure of generic companies, it is impractical for them to report international prices. Few generic companies operating in Canada sell their products in the 7 countries listed in the Regulations. Obtaining international prices is therefore impossible. A second issue is the fact that the generic price should be lower than the Canadian brand price. This makes international generic prices irrelevant to the work of the Board.

In addition to the problem of obtaining foreign generic prices, prices in this market segment are far more prone to variation caused by government intervention, discounting and other market factors. It is unclear how these prices would be of any assistance to the Board in determining if the Canadian price of a patented generic product is excessive.

Courts have ruled, most recently in the Leo case, that the Board has the right to assign different weights to the factors included in Section 85(1) of the Patent Act. This means the Board may assign a weight of zero where in its judgement, it is appropriate to do so. In addition, the Board has exercised its authority to differentiate what data should be filed for products in different categories. Veterinary and OTC drugs are examples. Given the highly questionable utility of foreign prices to the Board, the CGPA recommends the Board not use these in the price review process for patented generic medicines.

International prices should not be used in establishing or monitoring generic prices. The Canadian brand price is the only relevant marker for generic prices.

Thank you for considering our comments, and we look forward to provide further feedback on these issues.

Sincerely,

Jim Keon
President