Vernon Chiles

Memo

To: Ms Sylvie Dupont, Secretary, Patented Medicine Prices Review Board

From: Vernon Chiles

Date: March 3, 2008

Re: Options for Possible Changes to the Patented Medicines Regulations 1994 and the Excessive Price Guidelines

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1.0 KEY SUGGESTIONS

- Average prices as determined by PMPRB should be publicly available to ensure a competitive Canadian market for patented medicines.

- The Board should develop transparent policies so that excessive prices in the various market segments/customer classes are identified and no market segment/customer class should pay excessive prices.

- In accordance with the FCC ruling on the Dovobet matter benefits such as free goods and gifts should be consistently included when determining average prices (with the exception of samples and compassionate release). Subsections 4 (4) and 4 (5) of the regulations should make it clear that where concessions are provided to other than the direct purchaser they must be included in the calculations including concessions to governments in respect of publicly funded benefit plans, employers (public and private) in respect of employee benefit plans, and administrators of these plans (pharmacy benefit managers, insurance companies and others).

- Mechanisms should be established to permit re-setting the original MNE price where subsequent scientific or clinical or indications evidence show the initial MNE price determination to be no longer valid.

- The Board should explore whether the four factors in Section 85 (1) of the *Patent Act* remain sufficient for it to fulfill its mission.

- Revisions to the CPI methodology should result in neither large increases in average prices nor prices in any market segment or customer class that exceed MNE prices.

2.0 INTRODUCTION

I am a retired pharmacist living in Sarnia, Ontario. My comments on the options for changes are my own and reflect my view that medications should be available at non-excessive prices to all Canadians whether they are paid for:

- indirectly through taxes or

- indirectly through group arrangements such as employer or union sponsored plans or
- directly by citizens who lack public or private subsidization of their drug costs.

2.1 Core Assumptions

Support for the PMPRB Mission and Role

Given the increasing size of the pharmaceutical market and its increasing share of the total health system expenses the mission of the PMPRB to contribute to Canadian health care by ensuring that prices are not excessive is even more critical today than in 1987. The Board's mandate is to Canadians and not exclusively to governments and their drug benefit plans.

Patented Medicines

I accept the need to reward innovation through the *Patent Act.*

Atypical Nature of the Pharmaceuticals Market

The pharmaceutical market is not a normal "free market" since most drugs are ordered by a health professional who is not the payer and often not aware of the costs. The patient is not in a position to know the relative cost-effectiveness of the drug and its alternatives and furthermore may pay little or no money for the prescription and thus be unconcerned about cost. As a practising pharmacist I observed the effects of this atypical market. Where the patient has no coverage he/she may do without treatment due to a high cost relative to his/her ability to pay.

Where price competition occurs it is often to induce large payers such as governments to list drugs in their formularies. Price concessions may be in the form of payments to a government payer based on utilization rather than a lower formulary listed price.

The market for pharmaceuticals has grown much faster than most markets. Much of the reason for this is due to public and private subsidization arrangements. Given this level of subsidization costly new patented drugs can rapidly gain market share.

Efficiency

The Board should ensure that its policies and procedure do not result in undue costs for patentees and the Board itself. Policies and procedures should encourage a competitive pharmaceutical market that serves to lessen the frequency with which MNE prices occur.

3.0 OVERALL GUIDELINES REVIEW PAGES 4 TO 7

I participated in the Board's consultation process in November 2006. I also read the written submissions posted on the Board's website. I agree with the summary of the views of stakeholders that price reviews at the level of any market should be undertaken on a case by case basis where appropriate. However, the point was made that the identification of cases in need of investigation should not rely simply on serendipity; there should be a process to identify the cases. This seems not to be captured in the summary of views and is not adequately reflected in the proposals on page 4.

A fundamental principle should be that customers or market segments should not have to pay greater than MNE prices.

3.1 Proposal 1 page 4: At introduction the PMPRB will ensure that the average price for all markets does not exceed the MNE price. I support this proposal with major revision.

This proposal should also commit to ensuring prices not exceeding MNE prices for each class of customer and each province/territory in subsequent years. This is achieved by removing the words "At introduction".

3.2 Proposal 2 page 4: In future years if the Average Price for Canada appears to exceed the MNE price in any period…Board staff will review the price for each class of customer and each province/territory to determine in which market(s) the price appears to be excessive. I oppose this proposal.

The proviso, "…if the average price for Canada appears to exceed the MNE price in any period…" allows some segments of the market to pay in excess of MNE prices. For example, where the MNE price is $1.00 public plans might pay $.80 (net of benefits) and published prices paid in the private sector and listed in public and private formularies could be $1.15 giving an average price not exceeding $1.00. Thus this proposal results in a about 60% of the market paying above MNE prices but an average price less than the MNE price. The Board would then be allowing excessive prices in over half the Canadian market.

In cases where the average price exceeds the MNE price $1.15 would be considered excessive. Yet under this proposal $1.15 would not be excessive as long the average price does not exceed the MNE price. This is an inconsistent application of the Board's mandate. The Board's mandate is to Canadians and not exclusively to governments and their drug benefit plans.

3.3 Proposal 3 page 4: Review of prices in each market after a VCU or where subject to a Board order following a public hearing. This proposal is unnecessary if proposal 1 is adopted with my suggested change (3.1 above).

The commitment in this proposal to ensure prices not in excess of MNE prices complies with the Board's mission. However, as noted above in 3.0 and 3.1 the policy should be to ensure non-excessive prices in each market and there should be no need for such a special policy pursuant to a VCU or Board order after a public hearing.

3.4 Proposal 4 page 4: Any substantiated complaint of apparent excessive prices will be investigated. I support this proposal although average prices need to be made public for it to be fully effective.

Proposal 4 quite reasonably requires a complainant to substantiate his/her complaint. The Board does not make public the average prices. As a result the customer paying $1.15 in the example under 3.2 has no way of knowing that he/she is paying a price in excess of the average price and potentially in excess of the MNE price, neither of which is published.

PMPRB is the only organization that can determine average prices and should make this data public. This would enable customers and other market players to exert pressure to ensure a competitive pharmaceutical market and would, with the minimum of enforcement, decrease the prevalence of excessive prices.

The Board should develop transparent policies so that excessive prices in the various market segments/customer classes are monitored and enforced for all customers.

3.5 Re-setting the MNE Price page 5

I support the concept that the MNE price could be re-set where the initial categorization of the drug is found not to reflect all the circumstances (effectiveness, toxicity, indications) prior to a maximum period (e.g. 5 years) after the initial price review. This re-setting could result from the request of the patentee or from another source such as a payer. A re-setting process could result in a higher, the same, or a lower MNE price.

A point that was made vigorously at the consultation I attended was by a cancer specialist. He cited the example of a very costly drug for a rare cancer. From a societal perspective the high price could probably be justified, given the advance in therapy and the fact that the high per patient cost only applied to a small number of patients. He then pointed out that this drug subsequently got approval for a broader range of cancers and even other more common diseases. In this case a price that is originally justified becomes an exorbitant cost for the health system.

I am unclear as to whether the current four factors in section 85 (1) of the *Patent Act* provide the Board with the authority to deal with these types of cases. When the Patent Act was amended the drug portion of total health spending was much lower in both absolute and relative terms; also we did not have drugs that cost from $20,000 to $300,000 per year per patient. I suggest that the Board explore through the solicitation of expert opinion and public consultations whether it is appropriate to add factors to be considered in the determination of whether a price is excessive. An example is the case of very high cost drugs where the cost burden to the health system is demonstrably excessive. If this were done it would involve adding factor(s) by regulation as provided for in Section 85 (1) (e).

If such a review is impossible for the Board to initiate on its own my suggestion and similar comments could be brought to the attention of the Minister of Health.

4.0 OPTIONS TO ADDRESS ISSUES ARISING FROM THE FEDERAL COURT OF CANADA DECISION PAGES 11-15

The FCC ruling makes it clear that the broad range of concessions/benefits should be included in determining average prices. Major areas to address today relate to concessions being given to governments in respect of their publicly funded drug plans, especially in Ontario pursuant to Bill 102 and Quebec pursuant to Bill 130. This is expanding to other jurisdictions. These concessions must be factored into average price calculations for the Board's mission to be fulfilled.

Subsections 4 (4) and 4 (5) of the regulations should make it clear that where concessions are provided to other than the direct purchaser they must also be included in the calculations, including concessions to governments in respect of publicly funded benefit plans, employers (public and private) in respect of employee benefit plans, and administrators of these plans (pharmacy benefit managers, insurance companies and others).

4.1 Option 1 page 11: Maintain the current Regulations and respect the outcome of the FCC decision. I strongly support this option.

It complies with the Board's mandate and with the FCC decision. It should be improved by exempting compassionate release arrangements.

4.2 Option 2 page 11: Amend the regulations to exempt patentees from the requirement to report benefits (payments) provided to third-party payers (F/P/T) drug plans and potentially private insurers if similar payments are negotiated in the future. I strongly oppose this option.

Patentees consider government and private sector payers to be customers. They invest resources to ensure that prompt formulary listings under favourable terms are secured for their products. The decision made in the public sector has a profound influence on the extent to which a drug is used in the private sector. Public and private sector payers are customers just as much as are hospitals, wholesalers and pharmacies. Therefore financial concessions provided to these payers must be considered in determining average transaction prices [subsection 4 (4)] and in calculating net revenue [subsection 4 (5)].

Since other groups that monitor prices (e.g. IMS, Brogan Inc, Statistics Canada) have no access to data on off-invoice rebates and concessions to large payers it is critically important that PMPRB, for the benefit of Canadians, play its legislated role and determine the true average prices.

In summary the effects of Option 2 are:

- increased prices to other classes of customer to offset lost revenues to public payers and
- financial and health hardship due to higher prices for individuals with no or minimal drug coverage and
- lack of transparency in that the true average prices for Canada will be unknown and
- an abrogation by PMPRB of its responsibility to (a) ensure non-excessive prices for all Canadians and (b) monitor and report on the prices at which patented medicines are sold.

4.3 Options 3 (i) 3 (ii) and 3 (iii) on pages 13-14: Amend the regulations with respect to free goods. I oppose options 3 (i) and3 (ii) and support option 3 (iii).

Free goods supplied to a customer (e.g. buy one, get one free) should always be considered in determining the average price.

It is not entirely clear what circumstances are envisioned in the discussion of free goods to a particular customer class [3 (ii)]. Examples that occur to me are the situations where specific drugs are supplied to hospitals and specialized clinics in order to build market share in the broader market. People started on the drugs by the respected clinicians within the institution are likely to continue on them outside the facility. In addition, non-specialists are influenced to prescribe the drugs due to the respect in which the specialists are held. Certainly this type of free goods should be considered benefits in the context of subsections 4 (4) and 4 (5) of the regulations.

Where medicines are supplied as samples and never sold they should not be considered "free goods" and should not comprise part of the average price calculation.

Where drugs are supplied without charge as part of a compassionate release programme or as part of a research project they should similarly not be considered in the average price calculation.

4.4 Option 4 on page 14: Amend the Regulations to change "free services" to "services free or partially subsidized" in the calculation of the Average Price. I support this option.

It is unclear what services could be provided. Some could be clinical in nature (nursing or pharmacy services); others could be marketing or educational; still others could involve the financial subsidization of professional services by professionals and others. It is probably impossible to envision the scope of services that might be provided or subsidized and therefore it makes sense to include these services in the calculation of the average price whether entirely free or partially subsidized.

4.5 Option 5 on page 14: Amend the Regulations to exclude "gifts" from the calculation of the Average Price. I strongly oppose this option.

The discussion in which "gifts" are seen to be the types of gifts (computers, trips, other non-medicine goods and services) formerly supplied by patentees to physicians and now proscribed confuses me. There are several groups of potential recipients of gifts other than physicians.

My understanding of the subsections is that gifts are intended to include such things as different drug or cosmetic products, equipment, advertising, and trips in relation to the utilization of specific DINs. If this is correct "gifts" must be included in the calculation of the average price.

4.6 Option 6 on pages 14-15: Amend the Regulations to permit the Board to disallow any or all benefits which it determines pursuant to a public hearing, were implemented by a patentee for the purpose of reducing its liability in regard to excessive pricing in terms of the calculation of excess revenues. I support this option.

I particularly endorse the comment about "dumping" in the last paragraph of page 15.

5.0 GUIDELINE OPTIONS RE CPI ADJUSTMENT METHODOLOGY PAGES 16-17

I preface my comments on this section by stating that I have read the section several times and am unsure whether I have understood the options correctly.

5.1 Option 1 on page 16: Amend the methodology in the Guidelines for the establishment of the MNE price by using in the CPI-adjustment methodology the highest previous non-excessive average price, if the actual Average Price declines due to a new or increased benefit. I oppose this option.

Where the average price is lower than the MNE this may be by design. Patentees attempt to gain market share by providing lower than MNE prices to public (and possibly private) plans to get formulary listing. Listing on public plan formularies greatly helps gain market share in the private sector as well. After –say—two years with market share established the price could be raised across the board likely with some form of rebate arrangement as an offset for public plans. In this case private payers and individual citizens without coverage could be paying higher than MNE prices. I am concerned if this Option has the effect of allowing catch-up increases that result in higher prices for a large segment of the market.

5.2 Option 2 on page 17: Amend the methodology in the guidelines for the establishment of the MNE price by using the greater of the introductory MNE and the CPI-adjustment methodology using the highest previous non-excessive Average Price, if the actual Average Price declines due to a new or increased benefit. I oppose this option.

Patentees choose to sell at below MNE prices for market reasons. As noted above, this often occurs to achieve formulary listings. The comment that the disallowance of the right to increase prices to the MNE price level would be a disincentive is not valid. The need to sell the product is important to the patentee and if this cannot be achieved at MNE price levels the price must be lowered. Similar to my argument for Option 1 (5.1 above) an increase to the MNE price after a product is listed in good faith at a lower level is problematic.

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