Cummings Jewish Centre for Seniors
Guidelines Review

Any Market Price Review

The scenarios proposed permit the Board to review prices, at any other time, and that is advantageous. If, during the introductory period or in future years, the price is seen to exceed the MNE price then a review is warranted. The Board should not wait for a VCU or a hearing or complaints before initiating a review process. Notwithstanding this comment, and subsequent ones, the process of reviewing Average price for all markets will be an onerous one for the Board, more so than pricing for "Canada as a whole".

Re-setting the MNE Price

The making and marketing of drugs has been an issue discussed at length at the various meetings of stakeholders, and has yet to be resolved. An issue that arises, which we did not deal with, is the cost of advertising. There have been suggestions in various articles that advertising can, and often does, involve costs that are greater than those for R and D. To include these actual, full, costs in pricing MAY increase the MNE considerably, beyond the present MNE price tests. In such cases evidence is the critical issue, and then the Board could make a determination. The Board may need to re-perform a price test in current year to arrive at new MNE price.

When new scientific information becomes available, and re-categorization may be needed, this would also necessitate a review.

When considering the time frame for review, establishing ANY time frame (3 or 5 years) would be arbitrary. However, fewer than 3 years would not allow for new scientific information, or medical interactions to show up, or to complete clinical trials which, most often, take 3 years to be valid. Maintain the 3 year time frame for review and, when the med is sold in at least 5 countries, if possible, or which ever comes first. If only 3 countries are used then the price testing may be restricted to very high price comparator countries as well as incomplete scientific information.

Options Arising from FCC Decision

Regulatory Options

The Board, at present, has a great deal of discretion in considering average pricing of drugs, yet the FCC decision requires some tinkering. We would suggest Option 1, that is, maintain the current regulations. At the same time, option 6 should also be included. This gives the Board that necessary authority to determine when, or if, a patentee takes advantage of "benefits", which would include "freebies", after a price is considered excessive or following a hearing. This may appear contradictory, since the Board mandate is to consider prices of drugs "sold" in Canada. However, it is wiser to leave the discretion of including "benefits" in the hands of the Board rather than in that of the patentee. As it is, the patentee has the liberty to include certain "benefits" or not, to their advantage. Including the options in the guidelines, allows the Board to be selective in deciding which benefits are those that adversely affect pricing. A point to think about is, whether such "benefits" are included in the comparator countries that are used to establish the MNE price.

Guideline Options

Since the patentee already takes advantage of including, or not, certain benefits, then changing the CPI methodology according to Option 1 seems to make sense. When looking at Option 2, it would be interesting to know how many "reduced prices" there are. Reduced prices might be calculated through, or because of, "benefits". Frankly, we are uncertain how much advantage the patentee can take in pricing according to that Option, since there appears to be flexibility at present.

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