From: Lila Druckman [mailto:lwolfedruc@yahoo.ca]
Sent: Sunday, September 16, 2007 3:41 PM

Messages and Key concerns raised at bilateral meeting.....September 12, 2007

Re: Categories
It was noted that Category 3 drugs are brought to market much more often and in greater abundance than category 2 drugs and a key issue raised at the meeting was how to assess "moderate improvement" in the category 3 drugs...and whether or not the Board should allow a premium price for this particular therapeutic improvement.

The difficulty remains in determining the parameters that constitute a "moderate improvement" over an existing med. Some discussion involved looking at the "quality of life" that should improve with such a new delivery system or improved application, however, how would improved "quality of life" be determined since improved quality of life may be different for various patients? It might be useful to look at the possible side effects on patients, and convenience of dosage, since these can directly, and at times adversely, affect "quality of life".

Also, if there is moderate, yet, REAL improvement over an existing drug, should it then become a category 2 drug? By and large, determining what constitutes moderate improvement remains in a grey zone, and was left for the Working Group (to be assembled) to deal with. With these difficulties in mind, no premium should be given for this category 3, and in fact, (I feel that) "little or no improvement" should not even be considered.

Re : Making and Marketing...
It was revealed that patentees are not pleased about examining this issue in establishing guidelines for excessive pricing. All the more reason for doing so if the situation should arise. It was left to the working group, who will have more time for discussion, to examine how to classify costs of making and marketing of meds.

Re: International Therapeutic Comparison...
The question was raised regarding a method for identifying therapeutically comparable meds in comparator countries. This created some discussion, but, again, remains a difficult task and, hopefully, the working group will have more direct information from which to draw.

It was difficult, but understandable, to realize that because of the PMPRB activities, and our small market, patentees introduce new drug products 3-5 years after they have been sold elsewhere, thereby assuring a premium price (with the 7 comparator countries). Nevertheless, the PMPRB activities should be encouraged and applauded

Lila Wolfe-Druckman