Drs. Jean Gray, Mitchell Levine, James McCormack

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Dear Dr. Benoit:

As members of the Human Drug Advisory Panel (HDAP), we are the individuals who utilize and implement the Patented Medicine Prices Review Board Guidelines. We recognize both the strengths and the weaknesses in the current set of Guidelines and are aware that it will be difficult to establish a set of guidelines that will meet the needs of all users. Based on our experience, we would like to make the following observations and then follow with some suggestions for change:

- The existing categories are somewhat restricting. For example, in the past, Category 1 was used for a line extension or a generic equivalent with no real consideration of relative benefit except at the time of comparator selection. However, it is possible, although not common, that a reformulation of a drug can actually result in moderate improvement but we have no means of acknowledging that improvement.
- Category 3 medications can range all the way from a moderate improvement in treatment to no improvement at all. We would suggest that Category 3 be expanded to allow categorization of drugs into those that show a) little or no improvement in treatment outcomes and b) moderate improvement in treatment outcomes (but not achieving the clear standard established for Category 2 medications).
- HDAP struggles with the definition of what constitutes a "moderate or substantial improvement" in care. Often the data with which we work are very soft, address only a small niche of care of a particular disease, cover limited treatment intervals, and provide limited information about adverse effects. As an example, we have, on many occasions in the last couple of years, reviewed drugs for the treatment of cancer in which the outcome may be two to three months of increased survival but little or no information is provided about quality of life or possible adverse events. We struggle to determine whether this represents a "substantial" or a "moderate" improvement in care.

With this background, we would like to suggest for the consideration of the PMPRB that some minor changes be made in the categorization of drugs as well as in the process of choosing comparators for the purposes of pricing:

- Categorization. Each drug reviewed (whether current Category 1 or current Category 3) should be considered as either: a) little or no improvement in treatment or b) moderate improvement. Current Category 2 does not require modification and is relatively easy to determine. This would result in the category options being: 1a, 1b, 2, 3a, 3b.

- Recognizing that determining treatment outcomes for drugs introduced for the management of common diseases, such as asthma, hypertension, congestive heart failure, cancer, or chronic diseases such as rheumatoid arthritis, multiple sclerosis, etc. is often difficult, we would suggest that HDAP define what constitutes an improvement in care for each of these disease entities, including both risks and benefits of treatment, and then sends this document out to experts and other health professionals for their input. The resulting document could be posted on the PMPRB website. This parallel process could be used to help guide the HDAP and would make the process more transparent for industry, governments, and patient advocacy groups.
- Currently, the choice of comparators is usually, but not always, made by reviewing the ATC classification of the new drug, existing guidelines for treatment of the disease, and published evidence in the peer-reviewed literature. We would recommend that all three sources be used, without any hierarchy required, but that the process used in making the individual decisions of comparators should be explained.

Thank you for the opportunity to have input to the Consultation process. We look forward to the outcome of your deliberations.

Yours truly,

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