



THE PATENTED MEDICINE PRICES REVIEW BOARD'S APPROACH TO CATEGORIZING PATENTED MEDICINES FOR THE PURPOSE OF PRICE REVIEW

The Patented Medicine Prices Review Board (PMPRB) reviews the price of all patented medicines that are sold in Canada in order to ensure that they are not excessive.

When the Board's *Excessive Price Guidelines* were created, there was a view that not all medicines should be treated the same, as they represented varying degrees of innovation. The Board established three categories for the purposes of then applying non-excessive price tests.

The three categories can be summarized as follows:

Category 1 - New strength (e.g., 50 mg vs 100 mg) or new comparable dosage form (e.g., tablet vs. caplet) of an existing medicine

Category 2 - First drug product available in Canada that: (1) treats, effectively, a particular illness or addresses, effectively, a particular indication (breakthrough); or (2) provides substantial improvement in therapeutic effects, either because of increased efficacy or a major reduction in dangerous adverse reactions

Category 3 - Moderate, little or no improvement

For a more detailed description of the categories, please refer to the Board's *Excessive Price Guidelines*. (Reference Documents: Item 8 D)

The categorization of medicines is a scientific process. The Board considered it desirable to seek the advice of experts and established the Human Drug Advisory Panel (HDAP).

The mandate of the HDAP is to provide credible, independent and expert scientific advice regarding the scientific evaluation of patented medicines. The approach is evidence-based and the recommendations reflect medical and scientific knowledge and current clinical practice.

In its review, the HDAP reviews and evaluates the publicly-available scientific literature, including any submission by a patentee. In making its recommendations, the HDAP considers the different levels of evidence. Most evidence-based resources classify evidence according to the following hierarchy (with number 1 being the highest level of evidence):

1. Randomized controlled trials
2. Cohort studies
3. Case controlled studies
4. Case series
5. Expert opinion