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September 25th, 2007

Dr. Brien Benoit
Chairperson
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa Ontario K1P 1C1

2007 SEP 25 PM 3:51

Dear Dr. Benoit:

This letter is in follow up to the September 11th, 2007 bilateral consultation meeting between Rx&D and PMPRB Board and Staff.

While I appreciate the opportunity to provide feedback during this consultation on the PMPRB Guidelines, we question the PMPRB's motivation in undertaking the consultation. The current guidelines have been successful in achieving the Board's goal of ensuring the prices of patented medicines in Canada are not excessive. As shown in the PMPRB's own annual reports, including the latest produced in 2006, there is no problem of excessive pharmaceutical prices in Canada. Canadian pharmaceutical prices are, on average, below the international median of the PMPRB reference countries. Whether or not such complex and detailed Guidelines are required to accomplish non-excessive prices is an open question, but it is clear that the existing Guidelines have been effective, and there is clearly no need for more restrictive Guidelines or price tests.

From my perspective, problems do exist with the existing PMPRB Guidelines. Specific issues of note include:

- Increasingly inflexible application of the Guidelines by Board Staff, and increasing reliance on the hearing process;
- Lack of reward for incremental innovation;
- Ongoing PMPRB mandate expansion.

In recent years, Board Staff's role seems to have evolved from interpreting the Guidelines to rigidly enforcing them without taking advantage of the flexibility built into the Guidelines themselves, considering the factors in the Patent Act, or regard for past precedent. The increasing reliance on the hearing process to resolve pricing disputes is inefficient, costly, time consuming and, I would argue, in most cases unnecessary.

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The current Guidelines clearly fall short in rewarding incremental innovation. For example, under the existing Guidelines, new DINs of comparable dosage forms of existing medicines must be considered category 1 medicines, regardless of any clinical benefits they might provide over existing formulations. As well, category 3 combines medicines with moderate, little and no improvement over existing therapies and applies the same TCC test to those medicines. There can be a vast therapeutic difference between "no improvement" and "moderate improvement", and the lack of acknowledgement of such benefits by PMPRB does nothing to promote innovation.

Mandate expansion by PMPRB is an ongoing problem, with negative implications for the pharmaceutical industry, patients and the health care system. Parliament's original intent for PMPRB was to ensure prices of patented medicines were not excessive. Since PMPRB's inception, its scope has expanded to include: non-prescription drugs, veterinary drugs, medical imaging products, blood products, and vaccines. More recently, proposed amendments to the Guidelines sought to establish PMPRB as a full-blown regulator of prices, rather than monitor of excessive pricing, by proposing prospective price approvals. This "mandate creep" continues with the current Guideline consultation that includes discussion of regulating prices in "any market" and re-benching prices previously found to be non-excessive. As well, the decision to rescind the April 2000 Newsletter advice regarding compassionate use programs and to require reporting of rebates paid to provincial payers are also examples of the "mandate creep"

All of the issues highlighted above, inflexibility and reliance on the hearing process, lack of acknowledgement of the value of incremental innovation, and mandate expansion, contribute to uncertainty in the business climate for innovative pharmaceuticals.

Once again, I do appreciate the opportunity to provide additional feedback on changes to the PMPRB Guidelines, and I urge you to take this opportunity to establish a flexible, streamlined approach to executing the Board's mandate, keeping in mind that Parliament's intent in implementing the package of legislation that included establishing the PMPRB was not only protecting Canadian consumers from excessive prices, but also encouraging pharmaceutical innovation and investment.

Sincerely,

Chris Halyk
President
Janssen-Ortho Inc.