Backgrounder

Excessive price hearing:
Soliris (Alexion Pharmaceuticals Inc.)

About this hearing

- The Patented Medicine Prices Review Board (PMPRB) is holding a public hearing in the matter of the price of the patented medicine Soliris and Alexion Pharmaceuticals Inc. (Alexion), the pharmaceutical company that exercises patent rights for Soliris and sells the medicine in Canada.

- PMPRB staff investigated the price of Soliris and assert that the medicine is being sold in Canada by Alexion at an excessive price.

- Per the PMPRB's adjudicative process, the Board Panel will determine whether the price of Soliris is, in fact, excessive.

- In the event the Board Panel finds the price of Soliris to be excessive, it may order Alexion to reduce the price of Soliris and to offset any excess revenues it may have received through additional price reductions and/or a remedial payment to the Crown.

About Soliris

- Soliris is the first and only treatment for patients with Paroxysmal Nocturnal Hemoglobinuria, a rare and life-threatening blood disorder characterized by excessive destruction of red blood cells; and Atypical Hemolytic Uremic Syndrome, a rare and life-threatening genetic disorder characterized by blood clots in small vessels.

About PMPRB excessive price hearings

- The PMPRB last proceeded to an excessive price hearing in the matter of Sanofi Pasteur Limited and the medicines Quadracel and Pentacel, which was before the Board Panel between 2007 and 2012.

- It is always the PMPRB's preference to resolve matters consensually with patentees instead of proceeding to a hearing: many disputes are resolved through Voluntary Compliance Undertakings (VCUs), whereby the patentee agrees to adjust its price to adhere to PMPRB pricing guidelines.

- The PMPRB has initiated 29 public hearings since 1993. This includes Notices of Hearing that were subsequently settled through a VCU.

- Since 1993, the PMPRB has recovered over $157 million in excess revenues through VCUs. In 2015, five VCUs were accepted, with over $7 million in excess revenues paid back by patentees to the Crown, in addition to price reductions.

About the PMPRB

- The PMPRB is an independent, quasi-judicial administrative agency with a regulatory mandate to protect Canadian consumers from excessively priced patented medicines.

- The PMPRB sets the maximum price at which a patented drug can be sold based on the following factors:
    - the price of the drug in Canada;
    - the price in Canada of other drugs in the same therapeutic class;
    - the price in the PMPRB7 (France, United Kingdom, Sweden, Switzerland, Germany, United States, Italy) of the drug and other drugs in the same therapeutic class;
    - changes in the rate of inflation, as measured by the Consumer Price Index.

- In the context of a hearing, the Board Panel may consider additional factors it deems relevant in the circumstance of the case, including the cost of making and marketing the drug.

About the PMPRB's price review process

- Patentees must file price and sales information when their drug enters the Canadian market, and twice a year afterwards for each strength of each dosage form.

- PMPRB staff review the prices patentees charge for each individual patented drug product on an ongoing basis and will open an investigation into the price of a patented drug when any of the following criteria are met:
    - the price of a new drug product exceeds the PMPRB's price ceiling by more than 5%;
    - excess revenues for a new or existing drug product are $50,000 or more;
    - the PMPRB receives a complaint from the public about the price of a drug product.

- Where a drug appears to be excessively priced, the Board may hold a public hearing on the matter, which can result in an Order requiring the patentee to lower its price and/or pay back excess revenues to the Crown.

For more information or to schedule an interview, media may contact:

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