



Government of Canada's PMPRB price controls discourage rare disease medicines from coming to Canada

OTTAWA, ON, Oct. 23, 2020 /CNW/ - Canadian rare disease patients are worse off because of new price controls announced today by the federal Patented Medicine Prices Review Board (PMPRB).

"These changes run directly counter to the federal government throne speech commitment to pursue a national rare disease strategy," said Bob McLay, Chair of the Canadian Forum for Rare Disease Innovators (RAREi). "They have a disproportionate impact on the most vulnerable people in society."

McLay was responding to PMPRB's new pricing regime, which relies on new economic factors that disadvantage treatments designed for small patient populations, who often have life threatening illnesses. New regulated price reductions are uncertain and unsustainable for innovators, who already face myriad challenges bringing new rare disease treatments to Canada.

The new PMPRB guidelines have not lifted the cloud of uncertainty for launching new medicines in Canada for a number of reasons, including:

- While the PMPRB has provisionally limited the application of complicated economic factors in the short term, this could change at any time, as the approach hinges on a court challenge of the regulations, which is under appeal.
- The economic factors can still be used by PMPRB officials in investigations triggered by any complaint by anyone regarding the price of a medicine.
- As well, of particular concern for rare disease therapy developers, the PMPRB will apply a more restrictive use of the economic factors.

"Developing treatments for rare disorders is already an extremely risky and costly endeavour and these price controls create a massive barrier to entry in Canada," notes McLay.

RAREi, along with a long list of stakeholders (including provincial governments and agencies, health care professionals, health researchers and patients), has consistently expressed grave concerns about the impact of these changes on access to needed medicines.

RAREi calls on the federal government to revisit its new price controls and to arrive at a long-term, certain and sustainable approach for price regulation in Canada. There is a way to achieve the government's objectives without undermining a vital and vibrant industry sector that is committed to meeting the needs of rare disease patients in Canada.

About the Canadian Forum for Rare Disease Innovators (RAREi)

The Canadian Forum for Rare Disease Innovators (RAREi) is a group of the Canadian operations of global biopharmaceutical companies with a specific focus on researching, developing and commercializing treatments for rare diseases. Its members are: Alexion Pharma Canada Corp., Amicus Therapeutics, Inc., Biogen Canada Inc., Biomarin Pharmaceutical Inc., Horizon Therapeutics Canada, Ipsen Biopharmaceuticals Canada Inc., Mitsubishi Tanabe Pharma Canada Inc., Recordati Rare Diseases Canada Inc., Sanofi Genzyme, Sobi Canada Inc., Ultragenyx Pharmaceutical and Vertex Pharmaceuticals (Canada) Inc.

RAREi's input on the June 2020 PMPRB Guidelines along with other public consultation submissions can be accessed on its website at www.rarei.ca

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