

URGENT

Access to Trikafta: Act Now!

About the drug:

- Trikafta is a game-changing drug targeting the basic defect of cystic fibrosis. It can treat up to 90% of Canadians with CF.
- On October 21, 2018 the drug was approved for sale in the U.S.A., six months ahead of schedule. Ned Sharpless, acting FDA commissioner at the time of approval said: "...we used all available programs, including Priority Review, Fast Track, Breakthrough Therapy, and orphan drug designation, to help advance [Trikafta's] approval in the most efficient manner possible..."

Current status:

- Although the drug has breakthrough status in the U.S.A. the manufacturer has not yet even committed to applying to Health Canada for approval to sell the drug in Canada.
- Recent changes by the government to the Patented Medicines Price Review Board (PMPRB)
 could result in very large price reductions being imposed on patented medicines, even
 innovative, life-changing medicines like Trikafta. Some sources claim that the changes could lead
 to price reductions between 70%-90%.
- Businesses don't like uncertainty and these changes have created high uncertainty for companies who want to bring their medicines to Canada.
- The government has stated that it is committed to a separate, fast and fair review process.

Concerns and recommendations:

- Very large price reductions will make Canada an outlier compared to its OECD counterparts, and a low priority for drug launches.
- The uncertainty and the risk of dramatic price reductions are scaring companies, especially those with drugs for rare diseases like Trikafta. The PMPRB changes will delay and, in some cases, kill drug launches in Canada.

The changes to the PMPRB threaten access to CF drugs needed now. CF Canada is requesting that the PMPRB halt the implementation of the pricing changes until their impact on drugs like Trikafta can be properly assessed and changes made to ensure that drugs such as this one are quickly made available to Canadians.

What you can do:

- Send <u>this letter</u> to <u>PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca</u>. **The deadline is February** 14.
- Request a meeting with your elected officials. Tell them "There is a game-changing drug that can help 90% of the Canadian CF population but it is not available in Canada because our system is broken. We need the changes to the PMPRB put on hold until the impact on drugs like Trikafta

- can be properly assessed and changes made to ensure that drugs such as this one are quickly made available to Canadians. Ask them to raise this issue with the federal Minister of Health or their party leader.
- Become an advocate. Work with a team of CF advocates and participate in advocacy initiatives to improve policy for Canadians with CF. For more information write to advocacy@cysticfibrosis.ca.