



## Pfizer and BioNTech Receive Health Canada Authorization of COVID-19 Vaccine in Adolescents

May 5, 2021

- *Health Canada has authorized use of COVID-19 vaccine in adolescents aged 12 to 15 years under Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*

**KIRKLAND, QUEBEC and MAINZ, GERMANY, May 5, 2021** — [Pfizer Canada ULC](#) and [BioNTech SE](#) today announced that Health Canada has expanded the Interim Order authorization for their COVID-19 vaccine to include individuals 12 to 15 years of age. This is the first COVID-19 vaccine authorized in Canada for use in this age group.

“Today’s expansion of our authorization represents a significant step forward in helping the Canadian government broaden its vaccination program and begin to help protect adolescents before the start of the next school year,” said **Fabien Paquette, Vaccines Lead, Pfizer Canada**. “We are proud that we are playing a part of the efforts to help protect adolescent Canadians in this devastating pandemic.”

“Since securing the Interim Authorization in December for individuals 16 years and older, we have been working tirelessly to get our COVID-19 vaccine authorized around the world in order to provide access to as many countries as possible,” said **Özlem Türeci, Co-founder and Chief Medical Officer at BioNTech**. “I am proud of today’s expanded authorization of our COVID-19 vaccine, making it available for use in adolescents. Our work is not yet complete, as we continue our research into the use of our vaccine in pediatric populations.”

Health Canada based its decision on data from Phase 3 clinical trial in participants aged 12 to 15 years old. The trial enrolled 2,260 adolescents 12 to 15 years of age in the United States. All participants in the trial will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

In addition, the pediatric study evaluating the safety and efficacy of the COVID-19 vaccine in children six months to 11 years of age is ongoing.

The Pfizer-BioNTech COVID-19 vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (together with Pfizer), United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

### **AUTHORIZED USE IN CANADA:**

Pfizer-BioNTech COVID-19 vaccine is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. Pfizer-BioNTech COVID-19 vaccine must be injected intramuscularly only.

The use of Pfizer-BioNTech COVID-19 vaccine is permitted under an interim authorization delivered in accordance with [section 5 of the COVID-19 Interim order \(IO\)](#). Individuals should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada’s [IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#).

### **About Pfizer Canada**

Pfizer Canada ULC is the Canadian operation of Pfizer Inc., one of the world’s leading biopharmaceutical companies. Our diversified healthcare portfolio includes some of the world’s best known and most prescribed medicines and vaccines. We apply science and our global resources to improve the health and well-being of Canadians at every stage of life. Our commitment is reflected in everything we do, from our disease awareness initiatives to our community partnerships. To learn more about Pfizer Canada, visit [pfizer.ca](#) or you can follow us on [LinkedIn](#), [Facebook](#), [Twitter](#) or [YouTube](#).

### **About BioNTech**

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit [www.BioNTech.de](#).

### **Pfizer Contacts:**

Pfizer Canada Corporate Affairs  
1-866-9-PFIZER (1 866 973-4937)  
[corporate.affairs.canada@pfizer.com](mailto:corporate.affairs.canada@pfizer.com)

### **BioNTech Contacts:**

Media Relations  
Jasmina Alatovic  
+49 (0)6131 9084 1513  
[Media@biontech.de](mailto:Media@biontech.de)

