International

[CANADA] Regulatory Decision Summary - Pfizer-BioNTech COVID-19 Vaccine - Health Canada

Public Health Canada

https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00730

On December 9, Health Canada issued an interim authorization for the Pfizer/BioNTech SARS-CoV-2 vaccine to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) in individuals 16 years of age and older. Health Canada's analysis of the vaccine noted that the vaccine efficacy was evaluated to be 95% (with 95% confidence interval (CI) of 90.3% to 97.6%) in subjects without prior evidence of SARS-CoV-2 infection 7 days after the second administration of the vaccine. The most frequent adverse reactions in a random subset (N=8183) of study participants 18 years of age and older, who received the vaccine and were monitored for reactogenicity were: injection site pain (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%) and fever (14.2%) and were usually mild or moderate in intensity and resolved within a few days after vaccine administration. The unsolicited adverse events (AEs) reported in the study was lymphadenopathy (0.3%) with no medical sequela reported and lasted for on approximately 10 days. There were no safety signals identified and no life-threatening AEs and death related to the vaccine. Health Canada noted that one limitation of the data at this time is the lack of information on the long-term safety and efficacy of the vaccine.

[USA] FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine

U.S. Food & Drug Administration (FDA)

https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

On 11 December, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 16 years of age and older. The FDA's press release notes that, at this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person. The issuance of the EUA followed a meeting of the United States US Vaccine and Related Biological Products Advisory Committee (VRBPAC) on 10 December, to discuss recommendations regarding the US FDA's issuance of an Emergency Use Authorization (EUA) for the Pfizer/BioNTech SARS-CoV-2 vaccine. The meeting's agenda included discussions on vaccine safety and effectiveness monitoring, operational distribution plans, and a sponsor presentation. The New York Times reported that the VRBPAC panel voted 17 to 4, with one member abstaining, in favor of emergency authorization for people 16 and older. The article explained that some members expressed concern that there was not enough data from 16 and 17 year-olds to know whether the vaccine would help them, but the committee decided the benefits for that group outweighed the risks.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

New England Journal of Medicine (NEJM)

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577?articleTools=true

The New England Journal of Medicine (NEJM) published a study of the BNT162b2 COVID-19 vaccine. The study's results showed that among 36,523 participants who had no evidence of existing or prior SARS-CoV-2 infection, 8 cases of COVID-19 with onset at least 7 days after the second dose were observed among vaccine recipients and 162 among placebo recipients. This case split corresponds

to 95.0% vaccine efficacy Among participants with and those without evidence of prior SARS CoV-2 infection, 9 cases of COVID-19 at least 7 days after the second dose were observed among vaccine recipients and 169 among placebo recipients, corresponding to 94.6% vaccine efficacy. The study was not designed to assess the efficacy of a single-dose regimen. Of the 10 cases of severe COVID-19 that were observed after the first dose, only 1 occurred in the vaccine group. Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients with more reactions following the second dose. Most were mild to moderate and resolved rapidly. Limitations and remaining questions include: safety and efficacy beyond 2 months as well as groups not included in the trial (pregnant women, children, and those who are immunocompromised), if the vaccine protects against asymptomatic infection and transmission to uninfected persons, and how to deal with those who have missed the second vaccine dose. The study concluded that a two-dose regimen of BNT162b2 conferred 95% protection against COVID-19 in persons 16 years of age or older. Safety over a median of 2 months was similar to that of other viral vaccines.

Checklist to support schools re-opening and preparation for COVID-19 resurgences or similar public health crises

World Health Organization (WHO)

https://www.who.int/publications/i/item/9789240017467

The purpose of this checklist is to enhance compliance and adherence with the public health measures outlined in the recently-updated considerations for school-related public health measures in the context of COVID-19, particularly taking into consideration children under the age of 18 years in educational settings and schools with limited resources. It highlights the importance of multi-level coordination (i.e. national, subnational and individual school levels) and both participatory and co-designed approaches among various stakeholders (e.g. school staff, teachers, students and parents). This approach aims to optimise compliance with public health and social measures based on social and cultural contexts. The checklist is aligned with, and builds upon, existing COVID-19-related WHO guidelines and is structured around protective measures related to: 1) hand hygiene and respiratory etiquette; 2) physical distancing; 3) use of masks in schools; 4) environmental cleaning and ventilation; and 5) respecting procedures for isolation of all people with symptoms.

To Stop a Pandemic: A Better Approach to Global Health Security

Foreign Affairs

https://www.foreignaffairs.com/articles/china/2020-12-08/stop-pandemic

Jennifer Nuzzo is a Senior Scholar at the Johns Hopkins Center for Health Security, and Associate Professor at the Johns Hopkins Bloomberg School of Public Health. In her article, she argues for a fundamental re-imagination of how the world thinks about health security and pandemic preparedness. Among her list of recommendations: 1) strengthening pandemic governance, (enhancing International Health Regulations (IHR) by requiring countries open themselves up to inspection, creating incentives for countries to follow the IHRs, and strengthening the IHRs themselves); 2) enhancing surveillance efforts and encouraging the global sharing of information; 3) encouraging government to share samples of their pathogens; 4) increasing funding (creating a global health security challenge fund or for the World Bank to encourage poorer countries to use its grants and loans for pandemic preparedness); and 5) mitigating the risk and accounting for the possibility of an accidental or deliberate release of a deadly novel pathogen.