

**Q-283**

**Mr. Colin Carrie:**

With regard to Health Canada and the Pfizer/BioNtech Phase 3 vaccine clinical trial that was used for a population-wide approval of novel medical intervention: (a) what are, in percentages, the benefits conferred by vaccination versus control (placebo) considering all-cause morbidity (level 1 evidence of benefit or *harm*) in the said trial in terms of (i) adverse events, (ii) severe adverse events, (iii) serious adverse events, (iv) deaths; (b) what is, in terms of percentage, the amount that the vaccine reduced the transmission of COVID-19 in the vaccine arm compared to the placebo arm in the said trial; (c) what were the bio-markers for which trial participants were systematically tested at the commencement, during, and at the conclusion of the trial to test for the safety of the product evaluated in the said trial; and (d) what were, in terms of percentage, the absolute risk reduction provided by the vaccine?

**Mr. Adam van Koeverden (Parliamentary Secretary to the Minister of Health and to the Minister of Sport, Lib.):**

Mr. Speaker, Health Canada has authorized several COVID-19 vaccines for use in Canada. Each of these underwent a careful scientific review and met our standards for safety, efficacy and quality.

Information about all of the authorized vaccines can be found on the COVID-19 vaccines and treatments portal, <https://bit.ly/3EH07IB>, by clicking on the individual vaccine names and then the "all resources" tab. For each of the vaccines that have been authorized, detailed information can be accessed, such as the product monograph, which is the prescribing information for consumers and health care professionals on a manufacturer insert, the summary basis of a decision, which provides a detailed overview of the data considered by Health Canada, and the terms and conditions placed on the authorizations, which are the requirements for further data submission that manufacturers are required to meet.

Note that information in the portal is being updated regularly and can be found at <https://bit.ly/3lo1svI>. Also, the clinical study reports related to the approval of Comirnaty can be accessed on Health Canada's public release of clinical information website, at <https://bit.ly/3GFvDHE>. It has specific details related to various aspects of the review, including the summaries of clinical efficacy and safety.

Information on the questions regarding the trial, including those on adverse events and severe adverse events, the biomarkers for which trial participants were systematically tested, and on the absolute risk reduction provided by the vaccine, is all publicly available. The information can be found at <https://bit.ly/3HLiZYU>. Please note that how the vaccine reduced the transmission of COVID-19 in the vaccine arm compared with the placebo arm was not assessed during the said clinical trials.

For public convenience, here are some useful links. The product monograph for Comirnaty, with a date of revision of January 20, 2022, is at <https://bit.ly/3uEsNQF>, and the summary basis of decision for Comirnaty is at <https://bit.ly/3GNlhWg>.