Subject: RE: Philips Recall - FW: Health Product Complaint Form (FRM-0317A)

Dear Mr. Buell:

Thank you for your letter about the Philips Respironics recalls of CPAP machines, Bi-Level PAP machines, and mechanical ventilators. Your email was forwarded to the Medical Devices and Clinical Compliance Directorate (MDCCD) within the Regulatory Operations and Enforcement Branch at Health Canada for a reply.

The health and safety of Canadians is a top priority for Health Canada. Health Canada regulates the sale of medical devices in Canada and oversees the recalls associated with them. Manufacturers are required to have documented procedures in place to carry out an effective and timely recall. When a recall is conducted, the manufacturer is responsible for developing communications to inform affected parties of the recall, including recipients. More information is available in Health Canada's Guide to Recall of Medical Devices (GUI-0054).

I have taken note of your concerns and would like to provide you with the latest recall update as follows.

Health Canada is aware of the Type I recall initiated on June 14, 2021, by Philips Respironics Inc. of several models of its Continuous Positive Airway Pressure (CPAP) machines, BiLevel Positive Airway Pressure (BiLevel PAP) machines, and mechanical ventilators. The recalls were first posted on Health Canada's Recalls and Safety Alerts website on June 23, 2021.

Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BiPAP), and Mechanical Ventilators (RA-75889)

Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BiPAP), and Mechanical Ventilators (RA-75887)

Health Canada posted a public advisory on these recalls on July 30th, 2021.

The Department is monitoring the progress of this recall and conducting a continued risk assessment based on information from the manufacturer. Health Canada advises users of affected devices to consult their physician before stopping therapy or changing the way they use their device. Replacement of affected devices by Philips is expected to begin in 2022 and take approximately 1 year.

Health Canada has been working with Philips Respironics and other manufacturers in order to support mitigating shortages of medical devices impacted by the recall. At this time, Philips Respironics has reported 19 devices shortages related to this recall. Details on the shortages related to these recalls, as well as reporting requirements and other information about medical device shortages in Canada, can be found on Health Canada's website.

Information on the recalls provided by Philips can be found on the Philips recall website or by calling 1-877-907-7508.

To obtain further information on medical device incident reporting or recalls, please send an email to: hc.mdcu-ucim.sc@canada.ca.

Thank you,

Compliance and Risk Management Unit / Unité de conformité et gestion des risques
Regulatory Operations and Enforcement Branch (ROEB) / Direction générale des opérations réglementaires et de l'application de la loi (DGORAL)
Health Canada / Santé Canada