SOCIÉTÉ CANADIENNE DE THORACOLOGIE | CANADIAN THORACIC SOCIETY | Canadian Sleep Society | Société Canadienne du Sommeil

July 27, 2021

The Honourable Patty Hajdu
Minister of Health
70 Colombine Driveway, Tunney's Pasture
Ottawa, ON K1A 0K9

Sent via email: hcminister.ministresc@canada.ca

Dear Minister Patty Hajdu,

We are writing to **urgently** request a meeting with you or a member of your team to discuss the recall notice from Philips Respironics (Philips). Enclosed for your consideration is a position statement from the Canadian Thoracic Society (CTS), Canadian Sleep Society (CSS), and the Canadian Society of Respiratory Therapists, that outlines guidance to physicians and medical device distributors with regard to this recall.

As you know, Philips issued a voluntary recall notification in the USA for many of their positive airway pressure (PAP) devices and ventilators on June 14, 2021. This was due to possible harm secondary to breakdown of the polyester based polyurethane (PE-PUR) sound abatement foam. On June 23, 2021 Health Canada posted a medical device recall for the same products. The hazard classification is type II, defined as a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

Globally, the number of units affected is in the millions. Therefore, despite the efforts of PAP manufacturers, we expect future problems with PAP supply. There are risks associated with stopping Continuous Positive Airway Pressure (CPAP), and Bi-Level Positive Airway Pressure (Bi-PAP) devices abruptly in sleep apnea patients with significant comorbidities and/or substantial sleepiness, as well as patients treated for hypoventilation syndromes. This includes the re-emergence of excessive daytime somnolence and associated complications such as worsening sleep quality, quality of life, daytime function, and motor vehicle crash risk. There is also potentially worsening cardiovascular risk or respiratory failure.

We remain very concerned by the lack of information and support coming from Phillips, despite the fact that we are now several weeks into this recall from a global perspective. Please review the following key considerations and issues:

- Timelines for replacement or repair of devices by Philips are unclear, but may take many months. As noted, discontinuing treatment for prolonged time periods while waiting for replacement or repair may not be appropriate or feasible for many patients.

- There seems no plan in place from Phillips and no timelines in terms of whether or when the affected devices will be remediated and/or replaced.

- Other manufacturers will likely not meet increased demand for replacement devices, especially during a pandemic.

- The home sleep companies cannot be expected to have adequate supply of other CPAP/BiPAP devices to replace all the recalled Philips' machines. Please note there are limited options for BiPap.

- Who will pay for the substitution of devices even if it were feasible to replace the Philips devices with those from another company?

- The sleep labs will not be able to accommodate re-titrating all the severe patients or those with symptoms from using their Philips device who may need to switch devices.

Call to Action - We are calling on Health Canada to **urgently deal with potential shortages of devices to ensure Canada has an adequate inventory available**. We are also requesting responses to the following questions: Is Health Canada collecting information from practitioners and suppliers about patients who may have experienced side effects from using the Philips devices? Is there a national registry for this specific recall? Is Health Canada communicating with Philips to ensure the devices will be replaced quickly?

If you or a member of your team are available for a meeting with CTS and CSS executives in the coming weeks, please reply to this letter and we will coordinate meeting details.

We appreciate your consideration in advance.

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