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Deputy Minister

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Ottawa, Canada
K1A 0K9

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December 31, 2022

Mr. John Williamson, M.P.
Chair, Standing Committee on Public Accounts
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Mr. Williamson,

Health Canada is pleased to provide electronically, in both official languages, a progress report requested by the Standing Committee on Public Accounts pursuant to the Committee's Eleventh Report on *Securing Personal Protective Equipment and Medical Devices*.

Recommendation 3:

In [Report 10—Securing Personal Protective Equipment and Medical Devices](#), the Auditor General recommended that Health Canada should determine whether respirators are appropriately classified, given that Class I medical devices are not subject to a Health Canada review for safety and effectiveness. As committed in the Management Response and Action Plan developed in response to the Auditor General, Health Canada is aiming to complete an option analysis within one year of the end of the COVID-19 Pandemic.

As noted in our previous report to the Committee, Health Canada supports the Committee's recommendation and acknowledges the challenges associated with ensuring that the safety, effectiveness, and quality requirements for respirators are met in situations such as the COVID-19 pandemic.

During the COVID-19 pandemic, the Interim Orders allowed Health Canada to exercise flexibility for pre-market review of lower risk devices, including respirators, as well as post-market surveillance activities to prevent low quality respirators from entering and remaining on the Canadian market.

Health Canada anticipates publishing regulatory amendments when the *Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* expires in February 2023. The proposed regulations would introduce a new part to the

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Medical Devices Regulations with respect to COVID-19 medical devices. Within this framework, regardless of the class of the COVID-19 medical devices, Health Canada will be able to continue to conduct pre-market reviews and impose terms and conditions at any time on authorizations, strengthening our ability for oversight of medical devices that are authorized for use in relation to COVID-19.

In addition, Health Canada has launched its regulatory modernization agenda which aims to provide greater agility and enable an adaptive and modern licensing scheme for medical devices in order to effectively oversee them throughout their lifecycle. Health Canada took the first step towards this aim by pre-publishing proposed regulations amending the *Medical Devices Regulations* and the *Food and Drug Regulations* for public consultation in *Canada Gazette, Part I*, on December 17, 2022, as part of a regulatory proposal titled *Regulations Amending Certain Regulations Under the Food and Drugs Act (Agile Licensing)*.

In the context of its broader regulatory modernization agenda, Health Canada is committed to reviewing the classification of lower risk devices, including respirators, to ensure devices continue to be regulated using the appropriate level of oversight. Evaluating potential amendments to the medical device classification system is a complex task. Health Canada is taking a holistic approach to ensure coherence in its classification system. In-depth analysis is underway to help determine if respirators are appropriately classified and to inform options for potential adjustment if necessary. We are also conducting an international scan to ensure that our policy is aligned, where possible, with international partners.

Regardless of the class of device, if concerns about the quality, safety or effectiveness of any device, including respirators, are identified, Health Canada will take appropriate action to mitigate risks to Canadians. Health Canada remains committed to completing the deliverables captured in the Management Response and Action Plan developed in response to the Auditor General's Tenth Report, *Securing Personal Protective Equipment and Medical Devices*.

We trust that the Committee finds this progress update useful to their work.

Sincerely,

Dr. Stephen Lucas
Deputy Minister of Health