

# 5 - Guidance on the Use of Personal Protective Equipment

## KEY MESSAGES

- The Public Health Agency of Canada continues to work closely with Provinces and Territories to provide infection prevention and control guidance for a variety of health care settings, including long-term care facilities. The Agency has also provided advice to workplaces and businesses on how to reduce the risk of COVID-19 infections in the workplace, which may include the use of Personal Protective Equipment (PPE).
- This Agency has worked closely with provinces and territories, to develop evidence-based guidance on infection prevention and control for acute, long-term care and home care settings, including the appropriate use of PPE.
- The Agency has also provided advice to workplaces and businesses outside the health sector on how to reduce the risk of COVID-19 infections in the workplace, which may include the use of PPE in some workplaces.
- The Government of Canada continues to emphasize that physical distancing, hand hygiene and coughing or sneezing into your arm or sleeve are the most effective ways to prevent transmission of the COVID-19 virus.
- Wearing a non-medical mask or face covering when you cannot maintain a 2-metre physical distance from others is an additional measure you should take to prevent further transmission of the virus to others.
- Non-medical masks or face coverings are not PPE, but they are a way to prevent spread of the COVID-19 virus to others.

## KEY FACTS AND FIGURES

- Healthcare workers need medical masks, including surgical, medical procedure masks and respirators such as N95 masks.
- Non-medical masks for face coverings are not PPE, but they are a way to prevent spread of the COVID-19 virus to others.
- Canadian public health guidance related to COVID-19 has been adjusted as the evidence base and our understanding of COVID-19 evolves.

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### ***IF PRESSED ON USE OF NON-MEDICAL MASKS FOR HEALTHCARE WORKERS:***

- Healthcare workers need medical masks, including surgical, medical procedure masks and respirators such as N95 masks.

### ***IF PRESSED ON WHY POSITION ON MASK USE BY THE GENERAL PUBLIC HAS CHANGED***

- Canadian public health guidance related to COVID-19 has been changing as the evidence base and our understanding of COVID-19 is rapidly evolving. We are continually looking at the evidence as it is being produced and working with our partners across the country and around the world to learn more.
- Wearing a non-medical mask is an additional measure we should take to protect others, particularly when physical distancing is not possible in public settings (e.g., grocery shopping, in close settings such as public transit).

## **POSSIBLE Q&As**

### **Masks**

#### **Q1. Has Health Canada approved KN95 masks for use in Canada. If not why not?**

Yes, we have approved KN95 full face respirators in the context of the pandemic on the basis of equivalent standards to N95 respirators.

#### **Q2. Is the KN95 respirator NIOSH certified? Does it meet an equivalent alternate standard?**

No, KN95 respirators are not NIOSH certified. They meet GB2626-2006, which is an equivalent standard to NIOSH-42CFR84. Equivalencies for masks and other equipment can be found at <https://buyandsell.gc.ca/specifications-for-COVID-19-products#100>

#### **Q3. Can anyone sell a mask that is advertised for non-medical use? Does it matter if there is no English on the mask?**

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If not used in a clinical setting, and if it is explicitly clear in the product labelling that they serve a non-medical purpose (e.g., “not for medical use”, “industrial use only”), masks and respirators are not considered to be and are therefore not regulated by Health Canada.

### **Q4. What is the status of Health Canada’s review of the “WOODBIDGE INOAC MASK” and whether it can be used at hospitals?**

Health Canada has authorized the “WOODBIDGE INOAC MASK” on April 4, 2020. The device is intended to mitigate the wearer’s exposure to hazardous particles. This device is not an N95 respirator; it is a surgical mask Level 3 which can be used in hospitals settings in accordance with the manufacturer’s labelling.

### **N95 Masks – Decontaminating and Reuse**

### **Q5. What are the potential decontamination methods under evaluation?**

Several proposed systems of decontamination are being assessed in Canada and around the world. The decontamination systems already authorized (e.g., Stryker Sterizone VP4 Sterilizer, Sterrad sterilization systems, Steris sterilization systems, Clean Works Clean Flow Healthcare Mini, and Bioquell Hydrogen Peroxide Vapour Generator) use various methods including, vaporized hydrogen peroxide, ozone or ultraviolet light. There is ongoing evaluation of new decontamination methods as applications are submitted under the Interim Order for medical devices.

Health Canada assesses proposed methods to ensure they meet the standards required for safety, quality and effectiveness and that the requirements for the key performance and safety endpoints to ensure the integrity of N95 are maintained following reprocessing to the validated limit of reprocessing cycles.

### **Q6. Is there good evidence to support these methods?**

Although the virus that causes COVID-19 is a novel virus, evidence from previous studies using similar viruses supports the safety and effectiveness of some reprocessing methods.

Manufacturers will be required to provide evidence to demonstrate the safety and effectiveness of their selected method of decontamination.

At a minimum this includes:

- disinfection of all harmful organisms (e.g., bacteria and viruses) likely to be present in the standard medical setting;
- demonstration that respirator filter and fit performance are maintained;

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- evidence that there are no residual chemical hazards related to reprocessing; and
- ensuring adequate labelling that describes validated methods and reprocessing conditions applied to the respirator.

### **Q7. What are the drawbacks to reprocessing versus new masks?**

Health Canada recognizes that reprocessing single-use masks is one potential solution to provide continued access to masks for healthcare workers who rely on them for protection.

Instructions from each manufacturer of an authorized decontamination device should be followed.

Fit is an extremely important aspect of N95 use. The drawback for reprocessed N95 mask versus new mask is that the nosepiece has been bent and may not allow a good fit. This is why PHAC recommends that respirator be returned to the original wearer, to increase the likelihood of fit. Should the reprocessed mask be put back into general circulation, it becomes very important to undertake the standard user seal check and to only use those masks that fit the user's face.

### **Q8. Have other regulators approved decontamination methods? Are we also considering these?**

Health Canada is aware that a number of devices have received Emergency Use Authorization (EUAs) from the US Food and Drug Administration to reprocess N95 masks ([link](#)). Health Canada continues to evaluate guidance from other agencies such as the US Centers for Disease Control and Prevention (CDC) for optimizing the re-use of respirators.

### **Expediting Access To Hand Sanitizers, Hard Surface Disinfectants, Personal Protective Equipment And Swabs**

### **Q9. Were these changes made through new regulations?**

These are interim measures implemented given the unprecedented demand and the urgent need for products that can help limit the spread of COVID-19, including hand sanitizers, disinfectants and personal protective equipment (e.g., masks and gowns). This is not a new regulation.

### **Q10. What does this new rule mean?**

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It is an interim measure and expedited approach. It is meant to facilitate access to imported hand sanitizers and disinfectants that do not fully meet the regulatory requirements under the Food and Drugs Act. Health Canada will allow certain products to be sold in Canada under this interim measure, including:

- products that are already authorized for sale in Canada but are not fully compliant with Health Canada requirements (e.g., labelling in one official language, different packaging from what was authorized); and
- products that are not authorized for sale in Canada, but are authorized or registered in other jurisdictions with similar regulatory frameworks and quality assurances.

Health Canada will allow these low-risk products to be distributed in Canada to address the current shortage in supplies. The expedited process requires an attestation form that helps Health Canada maintain a record of all hand sanitizers and disinfectants on the Canadian market. As with all health products, Health Canada will continue to monitor the safety of these products once they are on the market and will take action to protect the health and safety of Canadians, if necessary.

### **Q11. Is Health Canada actively reaching out to manufacturers to get more products imported?**

Information about this expedited process was shared with all drugs, natural health products and medical device establishment licence holders and product licence holders in Canada and with relevant industry associations.

Products permitted to be sold under this interim measure are being added to the list posted on Health Canada's [website](#). At the time the advisory was posted on March 18, only hand sanitizers and disinfectants had met the criteria for sale under this interim approach. Since then, medical devices have been identified and will be added to the list in the coming days.

### **Q12. How are medical devices regulated in Canada? What are Class I devices?**

Canada takes a risk-based approach to the regulation of medical devices, where the level of review before approval depends on the potential risk that the use of the device presents. This approach balances the need to provide the healthcare system with timely access to new and innovative technology, with the appropriate level of oversight and time required to assess safety and effectiveness.

In Canada, medical devices are categorized into four classes based on the risk associated with their use, with Class I devices presenting the lowest potential risk (e.g., a mask or gown) and Class IV devices presenting the greatest potential risk (e.g., a pacemaker). Class II, III and IV medical devices must have a Medical Device Licence to be sold in Canada. Companies selling Class I medical devices in Canada are required

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to have a Medical Device Establishment Licence. However, during this pandemic situation, Class I to IV devices can instead receive authorization under the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19.

Health Canada is currently expediting its review of licensing applications related to any medical device related to COVID-19. In addition, as with hand sanitizers and disinfectants, Class I medical devices that may not fully meet all regulatory requirements and are notified to Health Canada under this interim measure are being allowed on the market.

### **Q13. How can consumers distinguish between a fraudulent product and a product imported through this interim measure?**

Health Canada will maintain an updated list of products sold in Canada through this measure on its website for consumers to consult.

Hand sanitizers and hard surface disinfectants authorized for sale by Health Canada have an eight-digit Drug Identification Number (DIN) or Natural Product Number (NPN) on the product label. These products are listed on Health Canada's Drug Product Database or Licensed Natural Health Products Database.

Class I medical devices are not licensed by Health Canada, but companies importing or manufacturing them do require a Medical Device Establishment Licence from Health Canada. These are listed on Health Canada's website.

If consumers see a hand sanitizer or disinfectant for sale that does not have a DIN or NPN on the product label and is not on the list identified in the advisory, or if they become aware of a company importing or manufacturing a class I device without the required licence, they are encouraged to report it to Health Canada.

COVID-19-specific medical devices authorized for sale by Health Canada are listed on Health Canada's website.

### **Q14. What else is Health Canada doing to improve the supply of health products during the COVID-19 pandemic?**

The Minister of Health signed an Interim Order on March 18, 2020, to speed up access to medical devices for COVID-19. The list of COVID-19 medical devices authorized under the Interim Order is available on Health Canada's website.

### **Q15. Can people obtain access to medical devices and drugs that have not been authorized in Canada, but are available in other countries?**

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Healthcare professionals can request access to COVID-19-related medical devices not yet licensed in Canada and drugs related to the management of patients with COVID-19 through Health Canada's Special Access Program (SAP). Applications are considered on a case-by-case basis.

For questions related to the SAP for medical devices, please contact the program via email.

### **BACKGROUND**

Canadian public health guidance related to COVID-19 has been adjusted as the evidence base and our understanding of COVID-19 evolves.

Healthcare workers need medical masks, including surgical, medical procedure masks and respirators such as N95 respirators. It is extremely important that we have enough supply of medical masks for healthcare workers where it is urgently needed for medical procedures and to care for individuals who have COVID-19.

### **Personal Protective Equipment (PPE) in healthcare settings**

The Public Health Agency of Canada's (PHAC) interim guidance on infection prevention and control in acute healthcare settings was updated in line with our approach to keep guidance current and to ensure we provide comprehensive recommendations based on the best available evidence. The guidance emphasizes the need for environmental and administrative controls in facilities to protect healthcare workers and patients, as well as the fundamental importance of training in the use of PPE. It indicates that droplet and contact precautions are appropriate for most patient care. Aerosol-generating medical procedures require N95 respirators along with other PPE. The guidance remains interim as it is subject to revision based on new scientific evidence.

In new technical guidance, PHAC recommends that all healthcare workers in acute care hospitals wear medical masks and eye protection/face shields for the full duration of a shift in acute healthcare settings. Wearing a medical mask throughout the duration of a shift is an important measure to help reduce the risk of transmission from a healthcare worker to a patient. This recommendation applies to healthcare workers who are in direct contact with patients, as well as environmental services staff working in patient care areas. In addition, any healthcare workers who have COVID 19-related symptoms should immediately go home and only return to work following the advice of their local public health units.

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Healthcare workers should refer to their province or territory's guidance, as well as facility policies on the use of masks, eye protection, and other PPE, including any PPE conservation strategies that are in place.

### **Public use of non-medical face coverings**

Wearing a non-medical mask or face covering in the community has not been proven to protect the person wearing it. However, with the emerging information regarding pre-symptomatic and asymptomatic transmission, and the goal to stop the spread of COVID-19, wearing a non-medical mask can be an additional measure that can be taken to protect others when physical distancing is not possible in public settings (e.g., grocery shopping, in close settings such as public transit).

Wearing a non-medical mask in the community does not mean you should stop practicing the public health measures that are known to work, such as physical distancing. All of the recommendations regarding staying home, physical distancing, and hand hygiene are based on what is known to work best to protect from infection. It is important that Canadians understand what wearing a mask will achieve, and that if they choose to wear non-medical masks, they need to use them safely. Non-medical masks will not prevent COVID-19 spread without consistent and strict adherence to good hygiene and public health measures, including frequent handwashing and physical distancing.

PPE may be an important component of infection prevention efforts in non-healthcare workplaces. However, the choice and use of PPE is based on occupational health and safety advice specific to the job and workplace. PHAC provides information to help employers and employees determine what infection prevention and control measures, which might include PPE, are necessary in their workplaces.

### **PARLIAMENTARY ANALYSIS:**

#### **Liberal Party of Canada (LPC)**

- LPC members have been supportive of government messaging on the use of non-medical masks.

#### **Conservative Party of Canada (CPC)**

- CPC members have been critical about the changes in guidance around the usefulness and suggested use of non-medical masks. They perceive the evolution of messaging to be a failure of public health advice.

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- CPC members have also expressed concern in how PPE is distributed to non-medical workers, such as with firefighters, postal workers, or funeral home workers.

### **Bloc Quebecois (BQ), New Democratic Party (NDP), Green Party (GPC)**

- The GPC has advocated for the regular distribution and use of masks for all citizens, as done by Thailand.
- NDP members have enquired about how businesses, like dental clinics, who previously had donated all their PPE supplies, will be able to acquire new PPE now that economies are opening up.