Media Lines

Counterfeit respirators

Issue Statement: During the COVID-19 pandemic, with an increase in N95 respirator demand and use, there have been questions around the safety and legitimacy of respirators available in Canada. Health Canada is aware that there are counterfeit respirators and medical masks being sold. Health Canada is taking steps to identify and address counterfeit products.

NOTE TO MEDIA RELATIONS: There are additional approved media lines on "U.S. FDA revises eligibility criteria for certain filtering facepiece respirators."

Key Messages:

- Health Canada is warning Canadians about the risks of using counterfeit respirators as they may not protect Canadians against the virus that causes COVID-19.
- If your mask is counterfeit, stop using it as it may not protect you against COVID-19.
- Health Canada is working to ensure that the medical devices available to Canadians meet standards of safety and effectiveness. The Department is monitoring the Canadian market for counterfeit devices and will continue to take action to prevent their distribution in Canada.
- Selling or advertising counterfeit health products is illegal in Canada. Health Canada takes the risks posed by these products seriously and takes action to address them.
- Canadians are encouraged to report to Health Canada if they suspect the false and misleading advertising or sale of products in Canada.

Supplementary Messages on Compliance and Enforcement Options

- If a person or company is found to be selling counterfeit products, a number of compliance and enforcement options are available to correct non-compliance or to mitigate a risk to Canadians, including on-site visits, recalls, public communications, and product seizures.
- Health Canada takes a risk-based approach that takes into account the circumstances of each case to protect the health and safety of Canadians.
- The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention.

Supplementary Messages on Canada's Supply of Personal Protective Equipment (PPE) and Medical Supplies

- Health care workers need medical masks, including surgical masks, medical procedure masks, and respirators, such as N95 respirators.
- The Government of Canada is helping to ensure that health care workers have the PPE and medical supplies they need. We are doing this through collaborative bulk

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procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.

- The Public Health Agency of Canada (PHAC) is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal, provincial and territorial ministers of health.

- PPE and medical supplies received by the Government of Canada, whether donated or procured, are verified by PHAC to ensure they meet Government of Canada technical specifications for healthcare settings for COVID-19, as available on the buy and sell website of Public Services and Procurement Canada. If PHAC cannot account for the quality of products, they will not be allocated to the provinces and territories for the front-line health care response.

- The process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to check for defects in design and construction, and tested to confirm they meet specifications for filtering face pieces.

Supplementary Messages on Market Authorization of N95 and KN95 Respirators and the Interim Order

- There are two main ways for companies to sell and import COVID-19 Class I medical devices to the Canadian market. They can apply for a market authorization by Health Canada through the Interim Order for Expedited Access to Medical Devices for COVID-19 pathway or the Medical Device Establishment Licence (MDEL) pathway.

- Health Canada reviews the scientific evidence provided by the manufacturers through the Interim Order Authorization pathway to support the safety and effectiveness of devices before issuing authorizations for these devices.

- N95, KN95 and equivalent respirators are Class I medical devices and therefore do not require product authorization prior to sale in Canada. However, to enable Health Canada to conduct a scientific review in advance of authorizing the sale of these devices, manufacturers are encouraged to submit applications through the Interim Order pathway as opposed to the MDEL regulatory pathway.

- Health Canada will continue to accept equivalent alternate standards to N95, including KN95, but will request evidence of quality manufacturing and validated test results from independent testing facilities before the Department will authorize such devices via the available filing mechanism of the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19.

Questions and Answers:

Q1. How are medical devices regulated?
In Canada, medical devices are regulated under the Medical Devices Regulations and are categorized into four classes based on the risk associated with their use. Class I devices present the lowest potential risk (e.g., a tongue depressor, masks, gowns) and Class IV devices present the greatest potential risk (e.g., a pacemaker).

Health Canada issues two types of licenses for medical devices:

- Medical Device Licences (MDLs):
    - Issued for specific products, authorizing manufacturers to sell a class II, III, or IV medical device in Canada.
- Medical Device Establishment Licences (MDELs):
    - Issued to class I medical device manufacturers, as well as importers or distributors of all 4 medical device classes, to permit them to import or sell medical devices in Canada.

Medical devices, including respirators, are subject to the requirements of the *Medical Devices Regulations* (MDR), including safety and effectiveness as per Sections 10-20 of the MDR. In addition, establishments involved in the importation and distribution of medical devices are subject to licensing requirements under a Medical Device Establishment Licence (MDEL) to ensure that the company has procedures in place to manage post-market risks, such as maintaining distribution records, complaint handling, recalls and mandatory problem reporting procedures.

MDEL holders have a responsibility to ensure that all medical devices imported into and distributed in Canada meet the requirements of the MDR, including verification of the authenticity of medical devices.

In the event that counterfeit products are identified on the Canadian market, Health Canada inspectors will conduct follow-up activities to determine the source in order to mitigate any risks and will take appropriate compliance and enforcement action to protect the health and safety of Canadians.

Q2. What is a counterfeit health product?

A counterfeit health product, including a mask, is one that is represented as, and likely to be mistaken for, an authentic product. Health Canada considers a medical device counterfeit when it:

- comprises non-authentic components,
- is deceptively labelled with respect to identity, composition, origin or source,
- has falsifications that may look genuine, or
- contains forgeries (e.g., printed labels).

Signs that a respirator may be counterfeit include:

- no markings on the respirator,
- no approval (TC) number on the respirator or headband,
- no U.S. National Institute for Occupational Safety and Health (NIOSH) markings,
- the incorrect spelling of NIOSH,
- the presence of decorative fabric or other decorative add-ons (e.g., sequins),
- claims that the product is approved for use by children (NIOSH does not approve any type of respiratory protection for children), or
- ear loops instead of headbands.

Counterfeit medical devices are placed on the market without a Health Canada assessment for safety, effectiveness and quality, and may pose serious health risks to Canadians. These products are being sold outside the legitimate supply chain, and it is therefore difficult to recall them if they are defective.

There are a number of compliance and enforcement options available to correct non-compliance or mitigate risks to Canadians, including on-site visits, recalls, public communications, and product seizures. Health Canada may also refer charges under the *Food and Drugs Act* to the Public Prosecution Service of Canada for potential prosecution. The courts have the sole discretion to impose fines.

The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention.

When Health Canada identifies counterfeit N95 respirators, the Department will ask the manufacturer to recall the product and destroy it. The product will also be included on the list of counterfeit products on Health Canada's public advisory (link).

The importation and sale of counterfeit medical devices constitute violations of the *Food and Drugs Act* and its Regulations.

Q3. How can Canadians avoid buying counterfeit medical devices online?
For Canadians who require a medical device, such as a surgical mask or respirator, look for the following possible warning signs when buying online.

When buying through a third-party site (an online marketplace) or auction:

- If a listing claims to be "legitimate" or "genuine," it's probably not.
- Review transaction history and feedback, if possible, although reviews are not always truthful. Most auction sites or third-party distribution networks provide a link to the seller of the item and their past sales. This is where buyers have the option to leave feedback regarding their experience with the seller, such as whether the buyer received the item as advertised, whether they received it in a reasonable amount of time, and whether the buyer was happy with the product. Many reviewers will report whether a product didn't work or whether it was cheap in construction.
- Does the price seem consistent with the product's value? (For example, is the deal too good to be true?)
- Look at the quantity a buyer has in stock. During a time of shortage, advertising "unlimited stock" could be an indication that the respirator is not approved.
- Does the seller break marketplace policy and hide their contact information within images to circumvent filters?

When buying directly from a website:

- Is the primary contact email address connected to the website or is it a free email account? Using a free email service may suggest that the seller is not committed to the domain.
- Look for poor grammar, typos and other errors.
- Watch for cookie-cutter websites, where the sellers interchange several websites, making mistakes, such as:
    - mixing up names or logos,
    - leaving the site partially unfinished with dummy text,
    - having blank pages or broken links, or
    - including a nonsense privacy policy.
- Domain squatting type activity (misspelling the website's name to closely resemble a legitimate one).

Q4. What role does the NIOSH approval and code number play in Canada? Is it used as a guide to determine whether masks are up to standards?
NIOSH evaluates, tests and certifies N95 respirators. The respirator must pass minimum performance requirements, such as filter efficiency and breathing resistance. All N95 respirators certified by NIOSH must have an approval number stamped on the mask, represented as TC-84A-####n.

Health Canada, the regulator for medical devices in Canada, accepts the NIOSH certification as an appropriate quality standard for N95 respirators used by health care providers.

Equivalent alternative standards are also acceptable. The N95 respirator is the U.S. NIOSH standard for respirators. KN95 is the Chinese standard for respirators, and FFP2 is the European standard. Commercial-grade and medical-grade N95 and KN95 respirators are similar with respect to their design, filtration performance and material standards. In Canada, it is the labelling, indications for use and claims that contribute to the classification of a product as a medical device.

Q5. How is Health Canada verifying the authenticity of respirators and masks?
Health Canada conducts inspections of Medical Device Establishment Licence holders located in Canada, which includes verifying the recall, complaint handling, mandatory reporting procedures in place, and reviewing the labels of each product that a company is selling, amongst other things.

As part of this process, Health Canada reviews NIOSH N95 product images, labeling and all required identifying features as specified by NIOSH (e.g., NIOSH authorization #, name of manufacturer, model #) and cross references this information with databases on the NIOSH website and with the published regularly updated NIOSH counterfeit list.

In addition, the Department has communicated with MDEL holders to inform them of their regulatory obligations to verify product quality and authenticity of devices to prevent the importation and distribution of counterfeit products in Canada.

For imported device products, at the border, the Canada Border Services Agency can refer shipments of health products, including respirators and other PPEs, to Health Canada. When a referral is received, Health Canada evaluates the product to determine whether it is in compliance with the Canadian regulations (i.e., product and/or importer has received any necessary and valid authorizations from Health Canada). Shipments of health products that are deemed non-compliant are refused entry into Canada, or may be seized by Health Canada.

Additionally, personal protective equipment and medical supplies received by PHAC, whether procured internationally or domestically, undergo quality verification by PHAC to confirm that they meet Government of Canada technical specifications for health care settings for the COVID-19 response. If PHAC cannot account for the quality, the product is not distributed to provinces and territories and is subsequently assessed by PHAC for potential use in non-medical settings.