Media Lines

Expediting access to hand sanitizers, hard surface disinfectants, personal protective equipment and swabs

Issue Statement: On March 18, 2020, Health Canada issued an advisory announcing that the department is taking steps to expedite access to hand sanitizers, hard surface disinfectants and personal protective equipment (PPE) to help limit the spread of COVID-19, as well as swabs for testing.

Key Messages:

- Health Canada's top priority is the health and safety of Canadians.
- In light of the unprecedented demand and urgent need for products that can help limit the spread of COVID-19, Health Canada is facilitating access to products that may not fully meet current regulatory requirements, as an interim measure.
- This includes hand sanitizers, hard-surface disinfectants and personal protective equipment (such as masks and gowns), as well as swabs.
- For example, Health Canada will allow certain products of these types to be sold in Canada without being fully compliant to regulatory requirements, including:
    - products that are already authorized for sale in Canada but are not fully compliant with Health Canada's bilingual labelling requirements (e.g., labelling in only 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 is also expediting approvals of products, as well as establishment and site licences related to these types of products.
- Health Canada is working with Public Services and Procurement Canada, and Innovation, Science and Economic Development to identify manufacturers and facilitate rapid access to these necessary products.
- Health Canada is strongly committed to ensuring the safety of products, including products brought to Canada through these measures.
- The Department will continue to update Canadians on any further efforts to increase supplies of health products that may be used to help combat the COVID-19 pandemic.

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Questions and Answers:

Q1. When will these products be made available on store shelves?
For hand sanitizers and hard surface disinfectants subject to this interim approach, products may be imported and sold as soon as companies have submitted a complete notification form that meets the established criteria.

For personal protective equipment (class I medical devices), products may be imported or sold immediately after Health Canada issues a medical device establishment licence. Health Canada is currently issuing these licences within 24 hours of receipt of a completed application.

Companies are working as quickly as possible to make products available on shelves.

Q2. 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.

Q3. If these products don't meet all of Health Canada's regulatory requirements, should Canadians be concerned about their safety?
No. While these products are typically subject to certain regulatory requirements, such as licensing and bilingual labelling, Health Canada is allowing these low-risk products to be distributed in Canada to address their current unprecedented demand to help slow the spread of COVID-19.

The expedited process requires companies to complete and submit a notification form that allows Health Canada to maintain a record of all hand sanitizers, hard surface disinfectants and personal protective equipment being sold in Canada under this interim approach. 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.

Health Canada will continue to use all tools at its disposal to expedite the supply of safe and effective health products related to COVID-19. However, the department is not providing blanket approval of unauthorized drugs or devices.

We will update Canadians with any new information as it arises.

Consumers and patients are encouraged to report any health product adverse events to Health Canada.

Q4. 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

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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 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.

Q5. 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.

Q6. 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.

Q7. Can people obtain access to medical devices and drugs that have not been authorized in Canada, but are available in other countries?
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.

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

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