Buying Medical Devices From the Internet

Updated:

April 2011

IT'S YOUR HEALTH



Buying Medical Devices From the Internet

The Issue

A growing number of Canadians are buying medical devices from the Internet. Many of the websites that sell medical devices are lawful businesses that provide a useful service.



However, others sell devices that may present serious health risks, and some may take your money and send no product at all.

If you plan to buy a medical device over the Internet, there are steps you can take to minimize your risks and protect your health.

Background

There are nearly 1,800 generic types of medical devices on the Canadian market. They range from pacemakers to diagnostic kits (like pregnancy tests), contact lenses and condoms. Canada's

Hqqf 'cpf 'Ftwi u'Cev defines a medical device as any article, instrument or apparatus intended to diagnose, treat, manage or prevent disease or other health conditions.

All medical devices sold in Canada must meet the requirements of the Canadian Ogf kecn/F gxkegu/Tgi wrc kqpu. This helps make sure that the products are safe and effective when used as directed. There are four classes of medical devices. According to the Regulations, Class II, III and IV devices must be licensed before they can be sold in Canada. For more information on how medical devices are classified in Canada, see the link in the Need More Info section. Class I devices present a lesser risk and do not need a licence.

In general, you should use medical devices as part of an overall approach to health that is supervised by a doctor or other health care professional. Medical devices can help you maintain and improve your health, but they are not intended to replace professional health care.

The possible benefits of buying medical devices online include convenience, privacy and pricing. But buying these



health products online can also present certain risks.

Risks of Buying Medical Devices From the Internet

If you buy a medical device from a website that is not trustworthy, any of the following could happen:

 You may get a device that does not meet Health Canada's requirements for safety, effectiveness and quality. Many types of medical



devices, like automatic blood pressure monitors and blood glucose monitors, must have a Canadian Medical Device Licence before they can legally be sold in Canada. When devices like these are sold online, they may not have the required licence.

- You may get a product that has been recalled because of safety concerns.
- You may get a counterfeit device (a lower-quality product falsely labelled as being a higher-quality brand).
- You may receive a product that has not been stored properly.
 Some medical devices must be refrigerated until used, while others should never be frozen or exposed to heat. When you order a device from an unreliable website, you do not know where the product has been stored or for how long.
- If you buy a second-hand (used) medical device, you may get a

product with parts missing, no warranty or no instructions. There may also be safety issues related to cleanliness.

Other potential problems related to the online sale of medical devices include:

- the sale of licensed devices (like contact lenses or hearing aids) that have not been fitted by a health care professional
- unproven claims for certain products (like claims that magnets can cure carpal tunnel syndrome and arthritis pain)

These situations could present the following risks to your health:

- You may not get the medical treatment that you need.
- You may change treatment doses or make lifestyle changes based on faulty results of devices that do not work properly, like blood pressure monitors or glucose test kits (including blood glucose meters and test strips).
- You may get an incorrect diagnosis that causes needless worry. It could also lead to medical tests that are unnecessary and may present a risk of side effects.
- You
 may try
 to use a
 medical
 device
 that can
 harm
 your
 health
 (e.g.
 contact



lenses that may damage your eyes if they have not been prescribed

and fitted by a health care professional).

There is also a risk that some website operators will cheat you by taking your money and sending you nothing in return.

Minimizing Your Risk

Before you buy a medical device from the internet:

- Ask your health care provider if the device you have in mind is right for your condition.
- If you are buying a device that requires a Canadian Medical Device Licence, make sure the device has the required licence. Glucose test kits and other medical test kits for home use require licences. So do automatic blood pressure monitors, batteryoperated toothbrushes and hearing aids. You can find out whether a device is licensed for sale in Canada or if the device has been recalled by visiting Health Canada's website. See the Need More Info? section for more on this.
- Ask the seller these questions:
 - > Is the device new or used? How old is it? Does it have an expiry date? Does it have all of its parts? Is there a warranty?
 - > Will the device come with its original packaging / labelling and a full set of instructions?
 - > Has the device been stored properly (for example, kept at the right temperature)?
 - > Is the device meant to be used by health care professionals? (If so, the instructions may be hard to understand and you may not

Buying Medical Devices From the Internet

Updated:

Santé

Canada

IT'S YOUR HEALTH



- be able to use the device properly or understand the results correctly.)
- Is the device easy to set up, operate, clean and maintain? Are replacement parts needed? If so, how often? Where can you get the parts and how much do they cost?

When making a purchase from the internet:

- Make sure the website is credible and reliable. Choose sites that post privacy and security policies that are easy to find and read. Avoid giving out personal information (like your Social Insurance Number, credit card number or medical history) unless you are certain the website will keep it private and will not sell it without your permission.
- Never do business with a website that:
 - refuses to give you a street address or a working telephone number



claims to have a "miracle cure" for any serious condition

After you buy a medical device from the Internet (or elsewhere):

- Follow up with your health care provider to make sure the device fits, works properly and that you are using it the right way.
- Do not make drastic changes to your treatment without checking with your health care provider.
- Report any problems with medical devices to Health Canada's Hotline at 1-800-267-9675 (toll-free in Canada).

Health Canada's Role

Health Canada regulates the safety, effectiveness and quality of medical devices imported into and sold in Canada. This is done through a premarket review (before product licensing is granted), and post-market surveillance of adverse events (after licensing). As part of this work, Health Canada monitors complaints about medical devices sold in Canada, and communicates safety information about medical devices to health care professionals and the public.



Need More Info?

To report problems with medical devices, visit Health Canada's Health Product and Food Branch Inspectorate web section at: www.health.gc.ca/inspectorate

For more information visit the following web pages:

- Health Canada's Medical Devices web section at: www.hc-sc.gc.ca/ dhp-mps/md-im/index-eng.php
- To find out whether a Class II, III
 or IV medical device has a licence
 from Health Canada, do an online
 search of Health Canada's Medical
 Devices database at:
 http://webprod.hc-sc.gc.ca/
 mdll-limh/index-eng.jsp

If your specific device is not listed, check to see if similar devices have been licensed by typing the generic name (for example, "automatic blood pressure monitor") in the "device name" field. If there are similar licensed devices, it means that your device also requires a Canadian Medical Device Licence. You can also send your questions by e-mail to device_licensing@hc-sc.gc.ca or by fax to 613-957-6345.

- Health Canada's Advisories,
 Warnings and Recalls related to
 medical devices at:
 http://www.hc-sc.gc.ca/ahc-asc/
 media/advisories-avis/
 index-eng.php
- Kall qwt "J gcnj, Buying Drugs over the Internet at: http://www.hc-sc.gc.ca/hl-vs/ iyh-vsv/med/internet-eng.php

 Køl[qwt"J gcnj, Medical Test Kits for Home Use at: http://www.hcsc.gc.ca/hl-vs/iyhvsv/med/medtest-eng.php

For more articles on health and safety issues, go to the *Kau'[qwt'] gcnj* web section at: www.health.gc.ca/iyh

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245*

Original: August 2006
©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, 2011
ISBN# H13-7/14-2011E-PDF
Catalogue# 978-1-100-17715-1