



BUYING MEDICAL DEVICES OVER THE INTERNET

The Issue

A growing number of Canadians are buying medical devices over the Internet. Many of the Web sites that sell medical devices are lawful businesses that provide a useful service. However, others sell devices that may pose 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 (e.g., pregnancy tests), contact lenses and condoms. Canada's Food and Drugs Act 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 Medical Devices Regulations. This helps ensure 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 are 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 pose a lesser risk and do not require a licence. In general, medical devices are best used 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 potential benefits of buying medical devices online include convenience, privacy and pricing. However, the online purchase of these health products can also pose certain risks.

Risks of Buying Medical Devices Online

If you buy a medical device from a Web site 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, such as automatic blood pressure monitors and blood glucose monitors, require a Canadian Medical Device Licence before they may be sold legally 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 due to safety concerns.
- You may get a counterfeit device (e.g., 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 Web site, 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 (e.g., contact lenses, hearing aids) that have not been fitted by a health care professional, and
- unproven claims for certain products (e.g., claims that magnets can cure carpal tunnel syndrome and arthritis pain).

These situations could pose the following risks to your health:

- You may not receive 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 (e.g., blood pressure monitors, glucose test kits, etc.)
- You may get an incorrect diagnosis that causes needless worry. It could also lead to further medical tests that are unnecessary and may pose 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 Web site operators will cheat you by taking your money and sending you nothing in return.

Minimizing Your Risk

Before you buy a medical device online:

- 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 before it may

legally be sold in Canada, make sure the device has the required licence. Glucose test kits (including blood glucose meters and test strips) and other medical test kits for home use require licences. So do automatic blood pressure monitors, battery-operated 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 Web site. 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 (e.g., kept at the right temperature)?
 - Is the device intended for use by health care professionals? (If so, the instructions may be hard to understand and you may not be able to use the device properly or interpret the results correctly.)
 - Is the device easy to set up, operate, clean and maintain? Are replacement parts required? If so, how often? Where can you get the parts and how much do they cost?

When making a purchase online:

- Make sure the Web site is credible and reliable. Choose sites that post privacy and security policies that are easy to find and read. Avoid giving out personal information (e.g., Social Insurance Number, credit card number or medical history)

unless you are certain the Web site will keep it private and will not sell it without your permission.

- Never do business with a Web site that:
 - refuses to give you a street address or a working telephone number; or
 - claims to have a "miracle cure" for any serious condition.

After you buy a medical device online (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 consulting 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 and sold in Canada. This is achieved through a combination of a pre-market review prior to licensing, 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?

Contact:

Marketed Health Products
Directorate
Health Canada
Tunney's Pasture
Ottawa, ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738
E-mail: MHPD_DPSC@hc-sc.gc.ca

Also, see Health Canada's information sheet on Medical Devices at:
http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/3kit-fiche/factsheet_fiches-info_14_e.html

For information on how medical devices are classified in Canada go to:
<http://strategis.ic.gc.ca/epic/internet/inimd-am.nsf/en/hi00047e.html>

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://www.mdall.ca/>
If your specific device is not listed, check to see if similar devices have been licensed by typing the generic name (e.g., "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.

For information on reporting problems with medical devices, visit Health Canada's Health Product and Food Branch Inspectorate Web site at:
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/index_e.html

For a list of Health Canada's Advisories, Warnings and Recalls related to medical devices, visit:
http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index_e.html

Also, see the following It's Your Health articles:
Buying Drugs over the Internet at:
http://www.hc-sc.gc.ca/iyh-vsv/med/internet_e.html

Medical Test Kits for Home Use at:
http://www.hc-sc.gc.ca/iyh-vsv/med/medtest_e.html

For additional articles on health and safety issues, go to the It's Your Health Web site at:
http://www.hc-sc.gc.ca/iyh-vsv/index_e.html

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