

Information Update - Unauthorized soft-shelled hyperbaric chambers may pose serious health risks

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OTTAWA, Oct. 25, 2019 /CNW/ - Health Canada is advising Canadians that soft-shelled hyperbaric chambers that are promoted online or offered as a service to treat a variety of medical conditions—including autism, cerebral palsy and migraines—are unauthorized medical devices and may pose serious health risks, including death.

Oxygen therapy using hard-shelled hyperbaric chambers is a well-established medical treatment where patients are placed in an oxygen-rich and pressurized environment. While Health Canada has licensed five hard-shelled hyperbaric chambers for sale in Canada, it has not licensed any soft-shelled devices, meaning they have not been evaluated for safety, quality and effectiveness.

To date, Health Canada has not received any evidence supporting the benefits of the soft-shelled version of these devices, and manufacturers have not demonstrated that the soft-shelled models are effective for treating any medical conditions.

Potential risks associated with the use of soft-shelled hyperbaric chambers include:

- fire or explosion as a result of static discharge within an elevated oxygen environment;
- disease spread through cross-contamination between users;
- damage to the ears, eyes, sinuses, lungs and teeth; and
- changes to blood sugar levels.

The risk of fire is significantly increased when the device is used in combination with an oxygen concentration device.

Under the *Medical Devices Regulations*, it is illegal in Canada to advertise medical devices for sale, to import them for sale, or to sell them without appropriate licensing.

To learn more, visit Health Canada's Hyperbaric Oxygen Therapy webpage.

Who is affected?

- Patients who are receiving treatments in a soft-shelled hyperbaric chamber

What should consumers do?

- Do not purchase soft-shelled hyperbaric chambers online or obtain treatment from third parties using these products.
- Consult your healthcare professional if you use or have used a soft-shelled hyperbaric chamber and you have concerns about your health.
- Check whether medical devices have been licensed for sale by searching Health Canada's Medical Devices Active Licence Listing.
- Report complaints involving medical devices, including the sale of unauthorized devices, to Health Canada.
- Stay connected with Health Canada and receive the latest advisories and product recalls.

What Health Canada is doing

Health Canada is asking companies that sell unauthorized soft-shelled hyperbaric chambers to immediately stop selling these devices and to conduct a recall. Health Canada is advising importers, distributors and manufacturers that it is illegal to advertise, import for sale, or sell these devices in Canada without appropriate licensing.

Health Canada is contacting provincial and territorial authorities, as well as clinics and other types of establishments that offer treatments with soft-shelled hyperbaric chambers, to advise them of the medical device licensing requirements and the risks associated with using soft-shelled hyperbaric chambers. The Department is also working with the Canada Border Services Agency to help prevent further importation of these unauthorized medical devices.

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