

Advisory - Unlicensed soft-shelled hyperbaric chambers may pose serious health risks

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Summary

Product: Unlicensed soft-shelled hyperbaric chambers

Issue: Soft-shelled hyperbaric chambers are being sold directly to consumers online or are being offered as a service (i.e., as a treatment). These devices may not be safe and may expose patients, or those in close proximity, to serious injury, including death.

What to do: Do not purchase soft-shelled hyperbaric chambers online or obtain treatment from third parties using these products.

Issue

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

Soft-shelled hyperbaric chambers may expose patients, or those in close proximity, to serious injury, including death. Risks include fire, spreading transmissible diseases 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.

Since first warning Canadians about the risks of using unlicensed soft-shelled hyperbaric chambers in October 2019, the Department has continued to take action to remove these products from the market and to respond to complaints.

In early 2020, Health Canada seized six unlicensed soft-shelled hyperbaric chamber units from distributors in the Province of Quebec. The models are:

- Yada Vertical Soft Shell Hyperbaric Chamber and Yada Horizontal Soft Shell Hyperbaric Chamber, manufactured by Yada
- Vitaeris 320 Horizontal Soft Shell Hyperbaric Chamber, manufactured by Oxyhealth LLC.
- Oxynova Serie 9 Horizontal Soft Shell Hyperbaric Chamber, manufactured by Oxynova

In September 2020, the Department seized three more unlicensed soft-shelled hyperbaric chamber units from a distributor in Alberta. The models are:

- Oxynova serie 7 Soft Shell Hyperbaric Chamber, manufactured by Oxynova
- Oxynova serie 8 Soft Shell Hyperbaric Chamber, manufactured by Oxynova
- Oxynova serie 9 Soft Shell Hyperbaric Chamber, manufactured by Oxynova

Health Canada will continue to take action with companies (importers, distributors and manufacturers) selling unlicensed soft-shelled hyperbaric chambers. Health Canada is also working with the Canada Border Services Agency to help prevent further illegal importation of unlicensed soft-shelled hyperbaric chambers.

It is illegal to advertise for sale, import for sale, or sell medical devices in Canada without appropriate licensing, under the Medical Devices Regulations.

While Health Canada has not licensed any soft-shelled hyperbaric chambers, oxygen therapy using hard-shelled hyperbaric chambers is a well-established medical treatment where patients are placed in an oxygen-rich and pressurized environment. Health Canada has licensed four hard-shelled hyperbaric chamber manufacturers in Canada.

To learn more about hard-shelled hyperbaric chambers, visit Health Canada's Hyperbaric Oxygen Therapy webpage.

What consumers should do

- Do not purchase soft-shelled hyperbaric chambers online or obtain treatment from third parties using these products.
- Consult your healthcare practitioner 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 unlicensed devices, to Health Canada.
- Stay connected with Health Canada and receive the latest advisories and product recalls.

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