Health Canada Santé Canada

Canada

Raising Awareness: Avoiding Unauthorized Health Products Online (Information Session for Health Care Professionals)

Border Operations Program – November 2022

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Overview

- Health Canada and the Border Operations Program's mandate
- Regulated health products under our legislation
- Drugs that are market authorized by Health Canada
- Risks of unauthorized health products
- Examples of unauthorized health products
- Health care practitioners: commercial activities
- Program supports for health care practitioners
- Recap
- How health care practitioners & Health Canada can work together

Health Canada and the Border Operations Program's mandate

Mandate: Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health, while respecting individual choices and circumstances.

The Border Operations Program is responsible for monitoring the compliance of imported health products with the *Food and Drugs Act* and associated regulations and safeguarding the Canadian supply chain with respect to health products.

Border Centres: key activities

- The Border Centre Program works in **partnership** with the Canada Border Services Agency (CBSA) to enforce requirements set out under *the Food and Drugs Act* and its Regulations related to the **import** and **export** of health products (i.e., medical devices, prescription & non-prescription drugs, and natural health products) at the border.

- The Program protects Canadians by conducting various compliance and enforcement activities, including:
  - Compliance promotion - responding to public inquiries/complaints, developing import/export guidance/outreach materials and training CBSA Officers on import requirements for health products
  - Compliance monitoring - identifying suspect adulterated and counterfeit products, as well as requesting target and port lookouts
  - Enforcement - conducting examinations of shipments referred by CBSA at various points of entry or remotely

Regulated health products within the Border Program's purview

Human Drugs

Veterinary Drugs

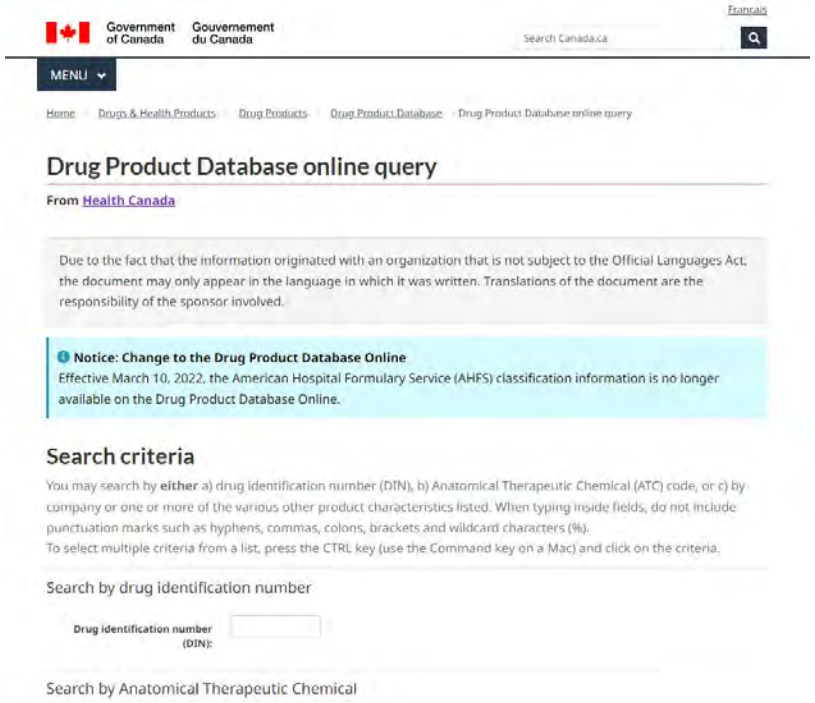
Natural Health Products

Medical Devices

Drugs that are market authorized by Health Canada

- Prior to receiving market authorization, drug products are reviewed by Health Canada for their safety, efficacy and quality

- Product licences granted to market authorized products:
  - Drugs: Drug Identification Number (DIN)
  - NHPs: Natural Product Number (NPN)
  - Homeopathic medicines: Homeopathic Medicine Number (DIN-HM)
  - Medical devices: medical device licences



Risks of unauthorized health products

- Product may be counterfeit or adulterated
- Possible side effects and drug interactions
- Drugs may be well past their expiry date
- No assurance that the drug is manufactured in a facility with acceptable hygiene and quality control standards
- No assurance that the drug has been manufactured, imported, or distributed in a manner to preserve its safety, quality, effectiveness
- Financial risk – the drug may not be shipped, or may be stopped by authorities

Unauthorized health products: examples of high risk health products relating to COVID-19

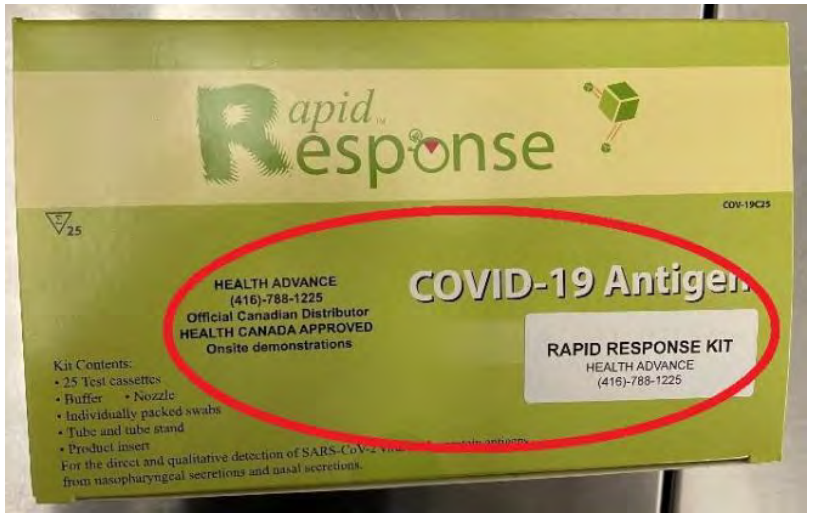
Expired COVID vaccine imported on July 29, 2021 with an expiry on June 23, 2021 (picture is unavailable)

Counterfeit N95 respirator

Counterfeit COVID test kit

Ivermectin

Hydroxychloroquine



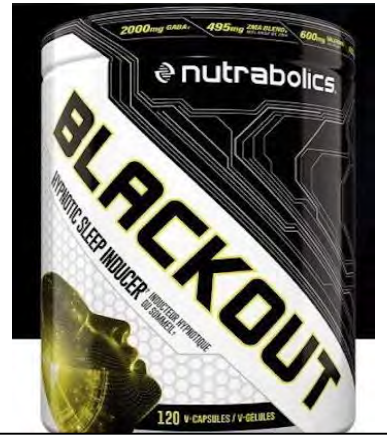
Unauthorized health products: counterfeit and adulterated products

Counterfeit Viagra

Counterfeit Botox

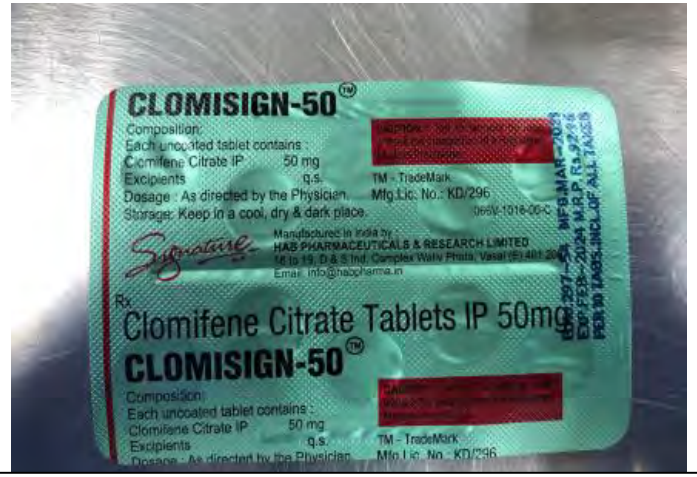
Counterfeit Juvederm

Rhino 69 Extreme 35000 – erectile dysfunction drug, unlicensed, contains Rx ingredient



Blackout – sleeping aid drug, unlicensed, contains Rx ingredient

Unauthorized health products: prescription drugs



Clomisign – infertility medication

Isotretinoin – cystic acne medication

Tamoxifen – breast cancer medication

Under *C.01.045 of the FDR*,

No person, other than one of the following, shall import a [human or veterinary] prescription drug

a) a practitioner*
b) a drug manufacturer
c) a wholesale druggist
d) a pharmacist or
e) a resident of a foreign country while a visitor in Canada

*As per the *FDR*, practitioner means a person who
(a) is entitled under the laws of a province to treat patients with a prescription drug, and
(b) is practising their profession in that province; *(praticien)*

Health care practitioners: commercial activities

- Activities that are considered commercial (i.e. sale)
- Health care professional (HCP) to use in their practice
  - HCP or a qualified investigator to use in a clinical trial or experimental study
  - Health care professional importing a drug on behalf of a patient (distribution)

- Licences/Authorizations required to import*
  - Drugs: Drug Establishment Licence (DEL)
  - NHPs: Site Licence (SL)
  - Medical devices: Medical Device Establishment Licence (MDEL)
  - Clinical Trials (drugs/NHPs) / Investigational testing (med devices) /Emergency Drug Release (Vet drugs): Authorization/No Objection Letters are issued
  - Special Access Program (Letter of Authorization)

**Under C.01A.002(1)(b) of the FDR, a pharmacist or practitioner is exempted from DEL requirements if they import or compound a prescription drug not commercially available in Canada, but what they import must be a licensed drug in Canada. If it is not licensed, HC's Special Access Program (SAP) may be applicable.*

Program supports for health care practitioners

Facilitating access to drugs for patients through other program means

- Special Access Program (human drugs and medical devices)
- Emergency Drug Release Program (veterinary drugs)
- Clinical Trials
- Access to Drugs in Exceptional Circumstances

Information available to support health care professionals

- Recalls and advisories
- Complaint and side effect reporting

Special Access Program (SAP) for human drugs and medical devices / Emergency Drug Release (EDR) for veterinary drugs

- For health care practitioners to access health products not available in Canada to treat patients with **serious or life-threatening conditions** or for **emergencies**
- Access to these health products is only considered when **conventional treatments have failed, are unsuitable or are unavailable in Canada**
- Not for research or to bypass clinical trial or drug/medical device review
- At the border: Letter of Authorization needed for importation

Clinical Trials

- Health care practitioners that are part of a clinical trial study team in Canada may import drugs to be used in that clinical trial or experimental study
- At the border: No Objection Letter (NOL) must accompany the shipment
- NOL is issued by the Pharmaceutical Drugs Directorate (PDD) (formerly the Therapeutic Products Directorate (TPD)) or the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) (formerly the Biologics and Genetic Therapies Directorate (BGTD)) of Health Canada authorizing the use of the drug for the trial

Access to drugs in exceptional circumstances

- Allows for the importation and sale of drugs that are not authorised in Canada but authorised for sale in countries such as U.S., EU or Switzerland to respond to an exceptional public health crisis.

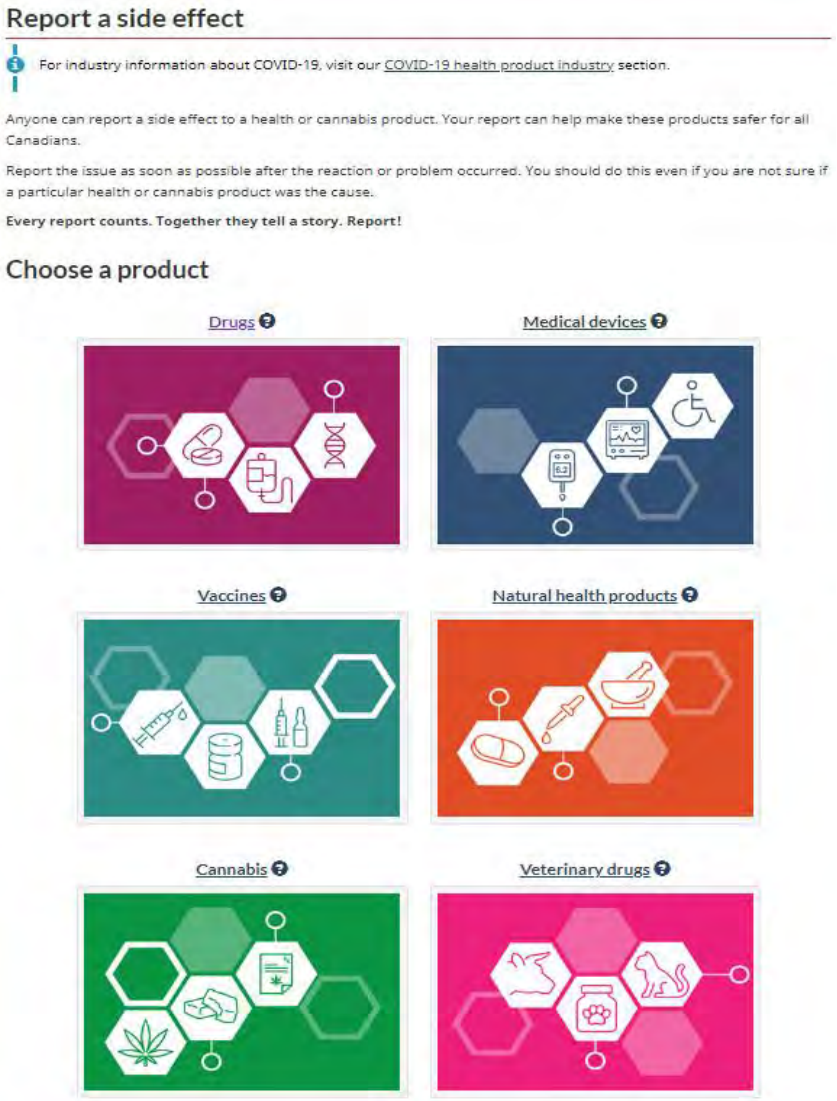
- Drugs that have been authorized under the Access to Drugs in Exceptional Circumstances pathway are found in The List of Drugs for an Urgent Public Health Need.

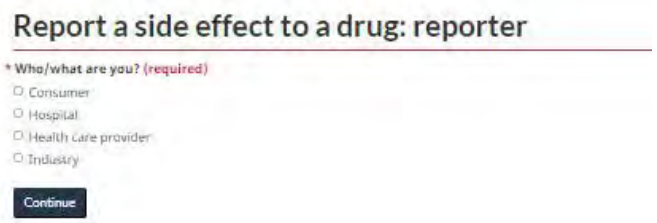
- At the border: The Notification of Importation Form must be used by importers to notify the Minister within 15 days after the importation of the drug into Canada.

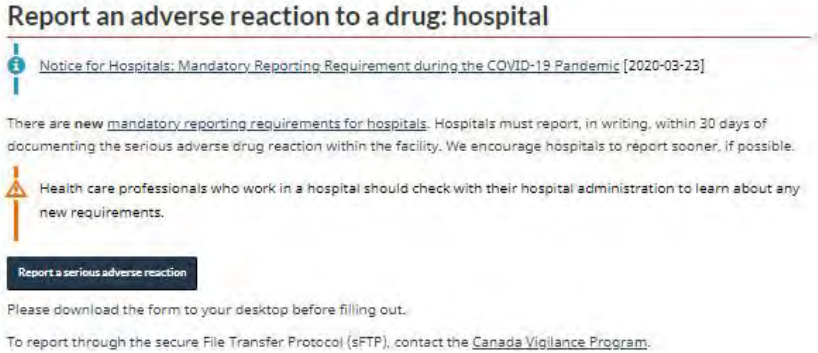
List of Drugs for an Urgent Public Health Need

Brand name Medicinal Ingredient(s)	Dosage form Strength Route of administration	Foreign identifying code or number	For Information Purposes		
			Foreign regulatory authority/ Foreign country	Canadian jurisdiction notifying for the drug/Date of notification by a public health official	Urgent public health need - Applicable Foreign Authorised Indication (Intended use or purpose of the drug)
Diaphin i.v. Diamorphine	Injectable 10 g/vial Intravenous	55561	Swissmedic/Switzerland	Public Health Agency of Canada - for use in all jurisdictions/ April 9, 2021	Opioid crisis – Substitution therapy in case of severe heroin dependence as part of a treatment program with prescription heroin.
Diaphin i.v. Diamorphine	Injectable 5 g/vial Intravenous	55561	Swissmedic/ Switzerland	Public Health Agency of Canada – for use in all jurisdictions/ November 1, 2021	Opioid crisis – Substitution therapy in case of severe heroin dependence as part of a treatment program with prescription heroin.
Diaphin IR 200 Diamorphine	Tablet 200 mg Oral	57724	Swissmedic/ Switzerland	British Columbia/April 14, 2021	Opioid crisis – Substitution therapy in case of severe heroin dependence as part of a treatment program with prescription heroin.

Side effect/adverse drug reaction reporting







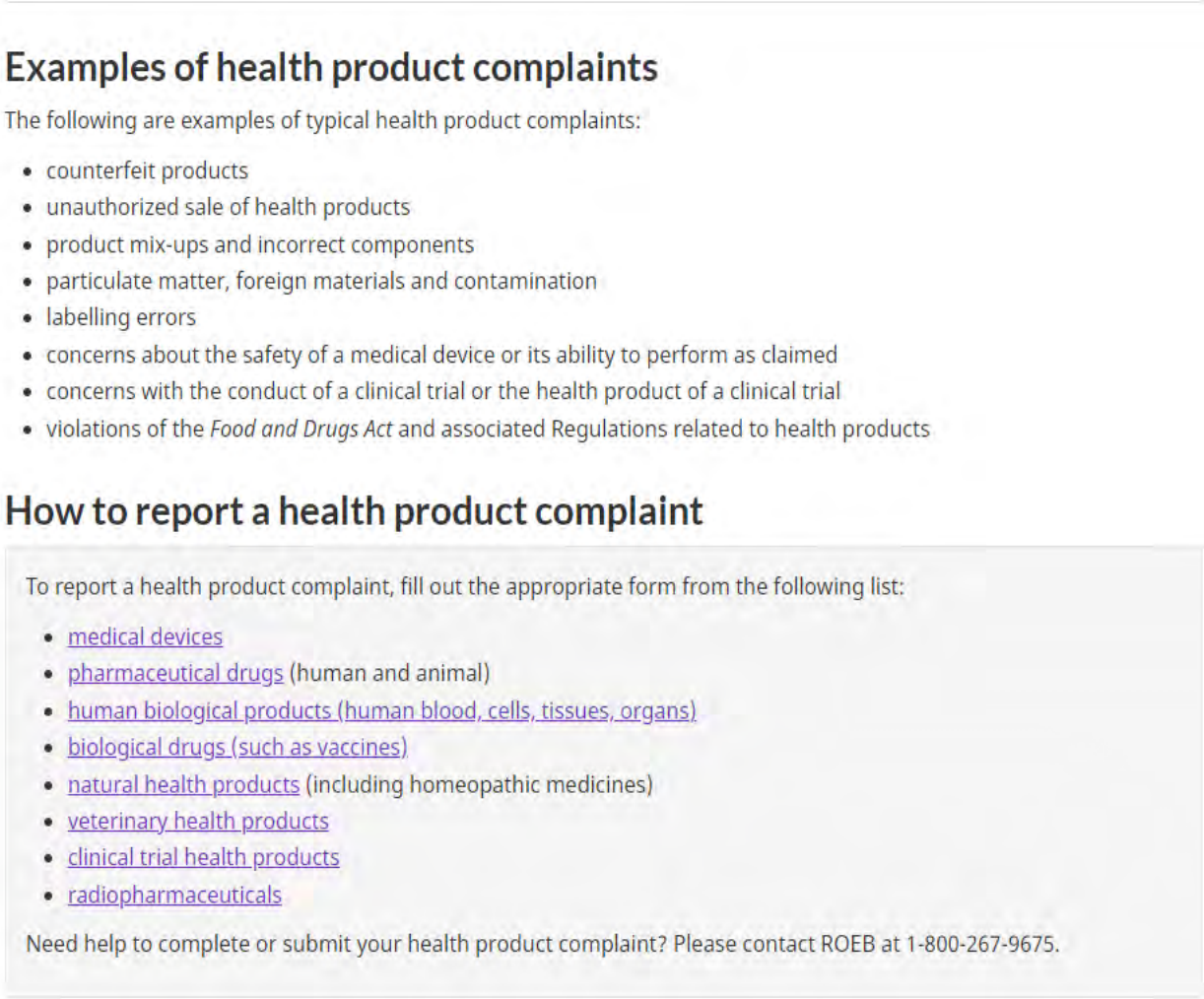
[Reporting a side effect online]

To submit a PDF form
Fax (toll free): 1-866-678-6789
Mail:
Canada Vigilance Program
Marketed Health Products Directorate
Health Canada
Address locator 1908C
Ottawa ON K1A 0K9

Health product complaint reporting

- Report complaints regarding health product safety (other than side effects).
  - health product quality
  - labelling errors
  - contamination, tampering
  - counterfeit products and the sale of unlicensed products on the Internet

- For health care professionals, consumers, and industry
  - medical device
  - drugs, natural health products
  - cells, tissues and organs
  - blood
  - assisted human reproduction material



Examples of health product complaints

The following are examples of typical health product complaints:

- counterfeit products
- unauthorized sale of health products
- product mix-ups and incorrect components
- particulate matter, foreign materials and contamination
- labelling errors
- concerns about the safety of a medical device or its ability to perform as claimed
- concerns with the conduct of a clinical trial or the health product of a clinical trial
- violations of the *Food and Drugs Act* and associated Regulations related to health products

How to report a health product complaint

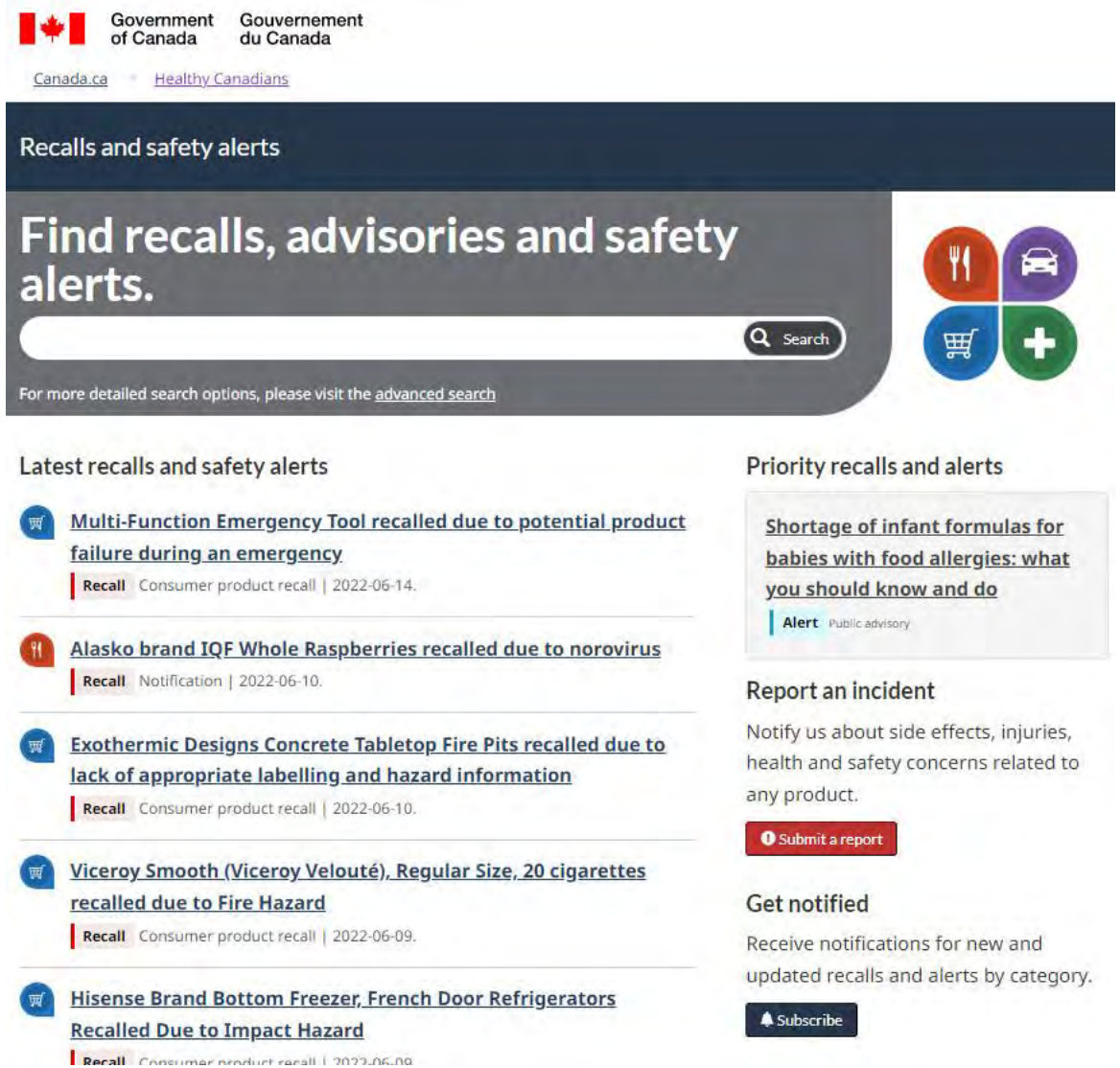
To report a health product complaint, fill out the appropriate form from the following list:

- medical devices
- pharmaceutical drugs (human and animal)
- human biological products (human blood, cells, tissues, organs)
- biological drugs (such as vaccines)
- natural health products (including homeopathic medicines)
- veterinary health products
- clinical trial health products
- radiopharmaceuticals

Need help to complete or submit your health product complaint? Please contact ROEB at 1-800-267-9675.

Recalls, safety alerts and advisories

- Recalls and safety alerts database
  - Provides centralized access to recalls, safety alerts, and advisories for:
    - drugs
    - natural health products
    - medical devices



Recap

- Unauthorized health products can pose various risks to health.
- Products authorized by Health Canada have been reviewed for quality, safety, and efficacy.
- C.01.045 of the FDR prohibits personal importations of prescription drugs for non-visitors to Canada or people whose primary residence is Canada.
- Commercial importations are not limited to retail sale, but include any form of distribution and require market authorization (product and importer).
- Health care professionals can import drugs for their patients in special circumstances through SAP and EDR.

Key messages (to share with patients)

- Prescription drugs are not permitted to be imported by Canadians, with the exception of returning from travels with medication obtained in Canada, or importing medication required to continue a treatment that had to be initiated while travelling abroad as a result of an injury/medical emergency.

- Buying health products online poses a risk to health because we do not know the origin of the product or if it was manufactured in sanitary conditions.

- If they choose to import prescription drugs into Canada, compliance actions may be taken (refusing entry to products or seizing the products).

How Health Canada and health care practitioners can work together

- Patient Handouts
  - Buying Drugs over the Internet
  - Choosing a Safe Online Pharmacy

- Where possible, examine health products with your patients
  - Help them recognize when a health product has been market authorized by Health Canada – DINs, NPNs, etc.

- Report any suspicious medications and side effects
  - Quality issues can be reported online through health product complaint forms, or by phone at 1-800-267-9675
  - Adverse drug reactions can be reported
    - through MedEffect online
    - by fax (toll free): 1-866-678-6789
    - by mail to the Canada Vigilance Program of Health Canada (address locator 1908C, Ottawa ON K1A 0K9)

Contact/support information

Phone: 1-204-594-8061

Toll Free: 1-833-622-0414 (Canada & USA)

E-mail: healthproduct-import-produitsante@hc-sc.gc.ca

Useful links:

GUI-0116: Bringing health products into Canada for personal use

GUI-0117: Importing and exporting health products for commercial use