

# **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



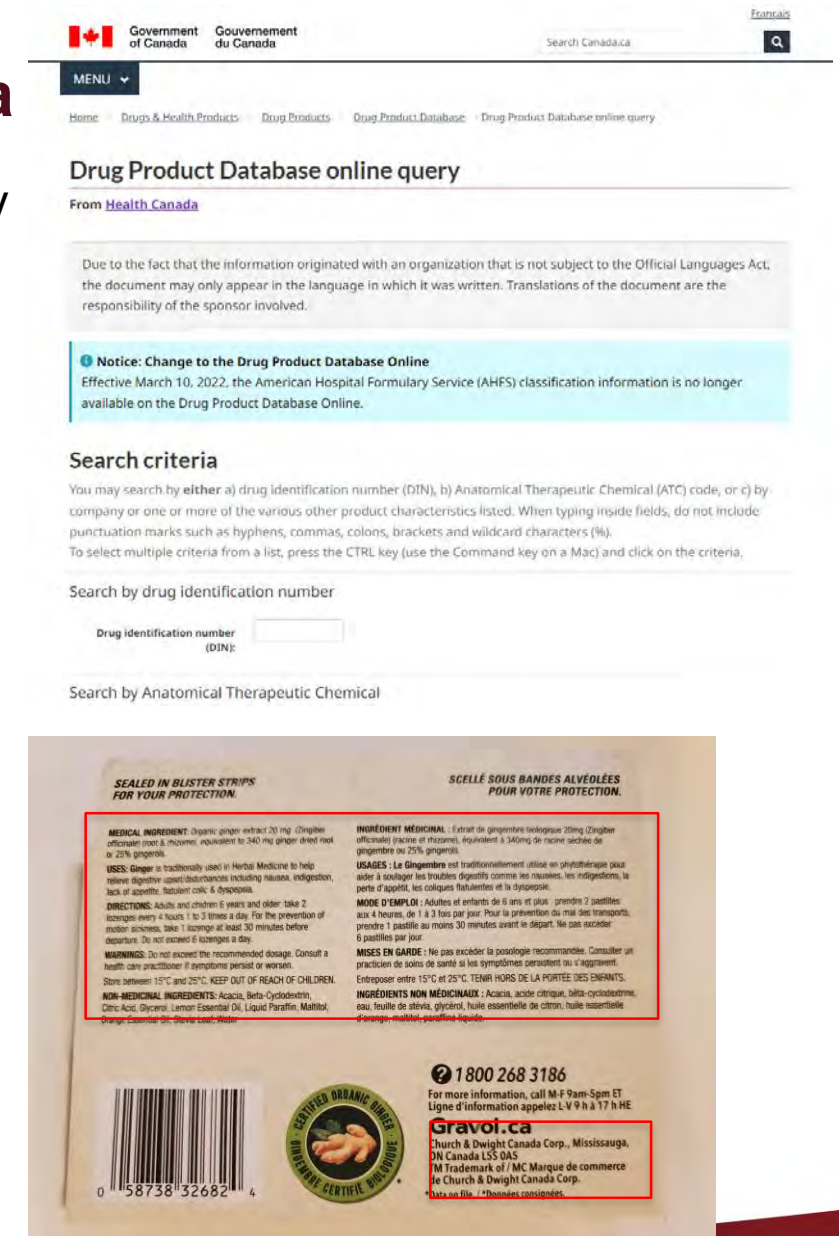
## Medical Devices





# 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

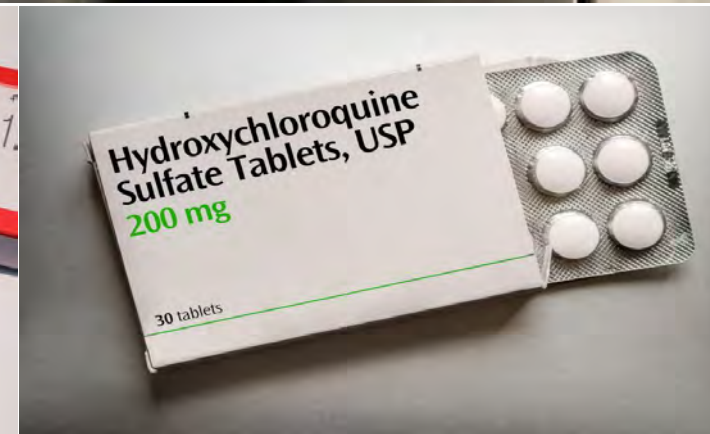
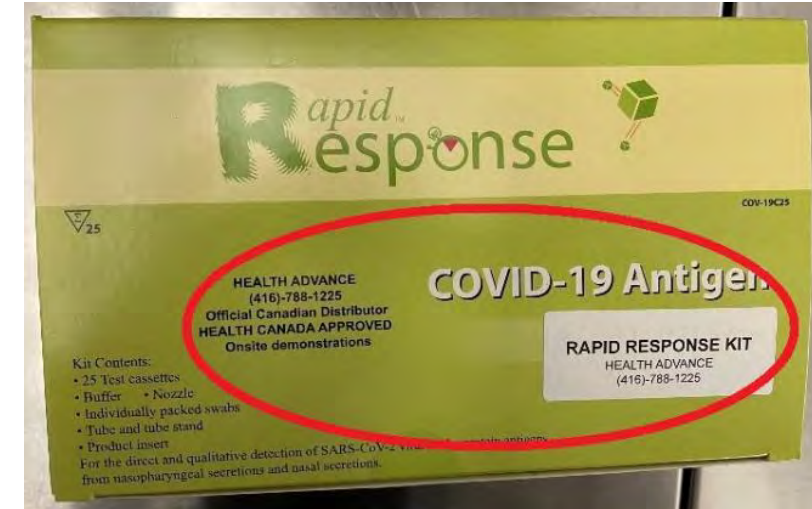
Expired COVID vaccine imported on July 29, 2021 with an expiry on June 23, 2021 (picture is unavailable)

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

## Report a side effect

For industry information about COVID-19, visit our [COVID-19 health product industry](#) section.

Anyone can report a side effect to a health or cannabis product. Your report can help make these products safer for all Canadians.

Report the issue as soon as possible after the reaction or problem occurred. You should do this even if you are not sure if a particular health or cannabis product was the cause.

Every report counts. Together they tell a story. Report!

## Choose a product

[Drugs](#)



[Medical devices](#)



[Vaccines](#)



[Natural health products](#)



[Cannabis](#)



[Veterinary drugs](#)



## Report a side effect to a drug: reporter

\* Who/what are you? (required)

- ☐ Consumer
- ☐ Hospital
- ☐ Health Care provider
- ☐ Industry

[Continue](#)

## Report an adverse reaction to a drug: hospital

Notice for Hospitals: Mandatory Reporting Requirement during the COVID-19 Pandemic (2020-03-23)

There are new [mandatory reporting requirements for hospitals](#). Hospitals must report, in writing, within 30 days of documenting the serious adverse drug reaction within the facility. We encourage hospitals to report sooner, if possible.



Health care professionals who work in a hospital should check with their hospital administration to learn about any new requirements.

[Report a serious adverse reaction](#)

Please download the form to your desktop before filling out.

To report through the secure File Transfer Protocol (sFTP), contact the [Canada Vigilance Program](#).

## Report a side effect

Drugs   Natural Health Products   Medical Devices   Review Decisions   Submit a report

About

Privacy Statement

About

Instructions

[Download PDF Form](#)

\* Mandatory Field

Complete all mandatory fields, marked by a \*, and provide as much detail as possible for the remainder of the report. Specific field instructions are included in the Instructions section above.

**A. Report and Reporter Information**

[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

The screenshot shows the 'Recalls and safety alerts' page from the Government of Canada. At the top, there is a header with the Canadian flag and the text 'Government of Canada' and 'Gouvernement du Canada'. Below this, there are links for 'Canada.ca' and 'Healthy Canadians'. The main heading is 'Recalls and safety alerts'. A large section titled 'Find recalls, advisories and safety alerts.' features a search bar with a magnifying glass icon and a 'Search' button. To the right of the search bar are four circular icons: a fork and knife (food), a car (vehicles), a shopping cart (products), and a plus sign (general). Below the search bar, a link says 'For more detailed search options, please visit the [advanced search](#)'. The page is divided into two columns. The left column, titled 'Latest recalls and safety alerts', lists five items: 1. 'Multi-Function Emergency Tool recalled due to potential product failure during an emergency' (Recall, Consumer product recall | 2022-06-14). 2. 'Alasko brand IQF Whole Raspberries recalled due to norovirus' (Recall, Notification | 2022-06-10). 3. 'Exothermic Designs Concrete Tabletop Fire Pits recalled due to lack of appropriate labelling and hazard information' (Recall, Consumer product recall | 2022-06-10). 4. 'Viceroy Smooth (Viceroy Velouté), Regular Size, 20 cigarettes recalled due to Fire Hazard' (Recall, Consumer product recall | 2022-06-09). 5. 'Hisense Brand Bottom Freezer, French Door Refrigerators Recalled Due to Impact Hazard' (Recall, Consumer product recall | 2022-06-09). The right column, titled 'Priority recalls and alerts', features a box for 'Shortage of infant formulas for babies with food allergies: what you should know and do' (Alert, Public advisory). Below this is a section 'Report an incident' with the text 'Notify us about side effects, injuries, health and safety concerns related to any product.' and a 'Submit a report' button. At the bottom right is a 'Get notified' section with the text 'Receive notifications for new and updated recalls and alerts by category.' and a 'Subscribe' button.

Government of Canada / Gouvernement du Canada

Canada.ca | Healthy Canadians

## Recalls and safety alerts

### Find recalls, advisories and safety alerts.

Search

For more detailed search options, please visit the [advanced search](#)

#### Latest recalls and safety alerts

- [Multi-Function Emergency Tool recalled due to potential product failure during an emergency](#)  
Recall | Consumer product recall | 2022-06-14.
- [Alasko brand IQF Whole Raspberries recalled due to norovirus](#)  
Recall | Notification | 2022-06-10.
- [Exothermic Designs Concrete Tabletop Fire Pits recalled due to lack of appropriate labelling and hazard information](#)  
Recall | Consumer product recall | 2022-06-10.
- [Viceroy Smooth \(Viceroy Velouté\), Regular Size, 20 cigarettes recalled due to Fire Hazard](#)  
Recall | Consumer product recall | 2022-06-09.
- [Hisense Brand Bottom Freezer, French Door Refrigerators Recalled Due to Impact Hazard](#)  
Recall | Consumer product recall | 2022-06-09.

#### Priority recalls and alerts

[Shortage of infant formulas for babies with food allergies: what you should know and do](#)  
Alert | Public advisory

#### Report an incident

Notify us about side effects, injuries, health and safety concerns related to any product.

[Submit a report](#)

#### Get notified

Receive notifications for new and updated recalls and alerts by category.

[Subscribe](#)

## 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](mailto: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](#)