



# Refills

Your dose of drug information in between details

April 2021

## Why and how should adverse drug reactions be reported?

### Why report adverse drug reactions?

- Some adverse drug reactions may become evident only after a health product (pharmaceutical, natural health product, radiopharmaceutical, disinfectant, vaccine or biologic drug) is used by patients or consumers. Your report helps indicate whether there is a potential safety issue with a particular health product
- Reporting suspected adverse reactions helps Health Canada monitor the safety profile of health products once they are marketed, to ensure that benefits continue to outweigh the risks

### What is Vanessa's Law?

- [Vanessa's Law](#) is named after Vanessa Young, a 15-year-old girl who died of arrhythmia and cardiac arrest after taking cisapride (Prepulsid®), which had been prescribed to her<sup>1</sup>
- Vanessa's Law is officially known as the [Protecting Canadians from Unsafe Drugs Act](#)
- Vanessa's Law was enacted in 2014. As of December 2019, it **mandates the reporting of serious adverse drug reactions and medical device incidents documented by hospitals**<sup>1</sup>
- Even if you do not work in a hospital, everyone is encouraged to voluntarily report. "Every report counts. Together they tell a story"<sup>2</sup>

### Which adverse drug reactions should I voluntarily report?<sup>3</sup>

- Any adverse reaction can be reported, even if you only suspect an association with a health product

#### Consider reporting especially:

- Unexpected reactions, regardless of severity
- Serious reactions, whether expected or not
- Reactions related to a newer health product (on the market for less than 5 years)

## Step-by-step guide

1. Report to the Canada Vigilance Program by visiting [Health Canada's Adverse Reaction Reporting](#) page  
**Exception: for vaccines administered in B.C.**, report to the BC Centre for Disease Control (BCCDC), who will send the information to Health Canada. See this [one-page resource](#) for instructions

### 2. Choose a product



### 3. Who/what are you? (required)

- Consumer
- Hospital
- Health care provider
- Industry

Follow prompts → Fill out form on website or download PDF and follow instructions

### 4. Fill out as much information as you can

For voluntary (non-hospital) reporting, you need all the information below to complete a report:

- [Reporter information](#) – your name and contact information
- [About the patient](#) – patient initials, age or sex
- [Information on the adverse reaction](#)
- [Suspected product](#) – only the drug name

5. **That's it. You're done!** By reporting, you can help improve health product safety for all Canadians

<sup>1</sup>Health Canada Overview of Vanessa's Law and reporting requirements; <sup>2</sup>Health Canada Adverse Reaction Reporting; <sup>3</sup>Health Canada Report a Side Effect