

# Serious adverse events related to cannabis used for medical purposes

CANADIAN PAEDIATRIC SURVEILLANCE PROGRAM  
2305 St. Laurent Blvd. Ottawa, ON K1G 4J8  
Tel: 613-526-9397, ext. 239  
Fax: 613-526-3332  
cpsp@cps.ca  
www.cpsp.cps.ca

## REPORTING INFORMATION

(To be completed by the CPSP)

Report number: \_\_\_\_\_

Month of reporting: \_\_\_\_\_

Province: \_\_\_\_\_

Today's date: \_\_\_\_\_

Please complete the following sections for the case identified above. If the information asked below is not readily available, please leave it blank. Strict confidentiality of information will be assured.

### CASE DEFINITION FOR SERIOUS ADVERSE EVENTS RELATED TO CANNABIS USED FOR MEDICAL PURPOSES

Report any serious or life-threatening adverse event\* in a child up to 18 years of age related to the intentional use of cannabis for medical purposes† Report an adverse event even if there is no certainty it is related to the use of cannabis.

Include any cannabis product from a licensed producer or private producer (home grown) such as dried cannabis to be smoked or vaporized, oils to be ingested or applied topically, and cannabis products taken by any other route of administration.

\* A serious or life-threatening adverse event is defined as a noxious and unintended severe response to a drug which occurs at any dose and results in emergency observation, hospitalization, persistent or significant disability, or death.

† Cannabinoids or cannabis used for medical purposes is defined as intentional cannabis use for any self-reported (or parent reported) health reasons, with or without physician authorization.

#### Exclusion criteria

- Adverse events resulting from recreational cannabinoid/cannabis use
- Adverse events resulting from accidental/unintentional cannabinoid/cannabis exposure (even if being used medicinally by another individual in the home)

## SECTION 1 – PROVIDER

1.1 Which of the following best describes your practice?

General paediatrician  Paediatric subspecialist; specify: \_\_\_\_\_

Other, specify: \_\_\_\_\_

1.2 First 3 digits of the postal code of your practice: \_\_\_\_ \_

1.3 Practice setting (check all that apply):

a)  Urban  Suburban  Rural/remote

b)  Academic  Non-academic  Does not apply

c)  Medical inpatient hospital ward  Intensive care unit (ICU)  Psychiatric inpatient hospital ward

Emergency department/urgent care centre  Other, specify: \_\_\_\_\_

## SECTION 2 – PATIENT DEMOGRAPHIC INFORMATION

2.1 Month/year of birth: \_\_\_\_ / \_\_\_\_  
MM YYYY

2.2 Sex:  Male

Female

Intersex

2.3 Gender:  Boy

Girl

Gender diverse

2.4 Province/territory where patient received medical care: \_\_\_\_\_

## SECTION 3 – CLINICAL PRESENTATION

3.1 Date of the reported serious adverse event: \_\_\_\_ / \_\_\_\_  
MM YYYY

3.2 Reported reason(s) for medical cannabis use: Condition: \_\_\_\_\_

Symptoms: \_\_\_\_\_  Unknown

3.3 Who identified the need for medical/therapeutic cannabis?

Parent  Child/youth  Physician  Other, specify: \_\_\_\_\_

3.4 What is the **primary** presenting condition of this serious adverse event (check **only one** category)?

- Sedation
- Coma *OR*  Reduced consciousness
- Euphoria or intoxication
- Cannabis withdrawal symptoms
- Cannabis use disorder
- Cannabis allergy
- Suicidal ideation or attempt
- Psychosis *If yes:*  Drug-induced psychosis *If yes:*  First episode  Recurrent  
 Schizophrenia  
 Other, specify: \_\_\_\_\_
- Affective/anxiety disorder *If yes:*  Depressive  Bipolar  Anxiety  
 Other, specify: \_\_\_\_\_
- Gastrointestinal problem *If yes:*  Cannabis hyperemesis syndrome  Nausea  
 Other, specify: \_\_\_\_\_
- Respiratory problem *If yes:*  Asthma attack (bronchospasm)  Respiratory depression  
 Upper or lower respiratory tract infection  
 Other, specify: \_\_\_\_\_
- Cardiovascular problem *If yes:*  Syncope  Ischemia/Infarcts  
 Other, specify: \_\_\_\_\_
- Neurologic problem *If yes:*  Seizure  
 Other, specify: \_\_\_\_\_
- Other, specify: \_\_\_\_\_

**SECTION 4 – RELEVANT MEDICAL HISTORY**

- 4.1 Has the patient had a prior emergency room visit or hospitalization for a cannabis-related adverse event?  
 Yes  No  Unknown
- 4.2 Does the patient have any known allergies to food or drugs?  Yes  No  Unknown  
*If yes, list allergies:* \_\_\_\_\_
- 4.3 List any pre-existing medical conditions (related or not to the reason for cannabis use): \_\_\_\_\_  
 \_\_\_\_\_
- 4.4 List all other concomitant medications or substances (including alcohol, tobacco, or natural health products):  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**SECTION 5 – TREATMENT AND OUTCOMES**

- 5.1 Outcomes attributed to the reported condition (check all that apply):
  - Observation in emergency department
  - Hospitalization *If yes, (check all that apply):*  Inpatient bed  
 ICU/PICU bed  
 Psychiatric bed  
 Specify: Length of stay \_\_\_\_ days  Patient is still in the hospital
  - Confirmed permanent disability *If yes, specify:* \_\_\_\_\_
  - Possible permanent disability *If yes, explain:* \_\_\_\_\_
  - Death

5.2 Treatment provided (check all that apply):

Does not apply (death prior to treatment)

Medical

*If yes, check all that apply:*

Adolescent medicine consultation

Fluids *If yes:*  IV  Oral

Ventilation assistance *If yes:*  Intubation  Non-invasive

Vasoactive drugs

Blood transfusion/colloid solutions

Renal assistance (i.e., hemodialysis/hemofiltration)

Other, specify: \_\_\_\_\_

Surgical

*If yes, specify:* \_\_\_\_\_

Mental/psychosocial

*If yes, check all that apply:*

Psychiatry consultation

Other mental health professional consultation

*If yes, check all that apply:*  Psychologist  Social worker

Addiction worker  Youth protection worker

Other, specify: \_\_\_\_\_

5.3 Did the patient continue to use cannabis/cannabinoids?  Yes  No  Unknown

**SECTION 6 – CAUSALITY**

6.1 Regarding the primary presenting condition, cannabis use for medical purposes was the (check only one):

Unlikely cause  Possible cause  Probable cause  Definite/certain cause

(For more information on the World Health Organization’s *Safety Monitoring of Medicinal Products* causality categories visit <http://apps.who.int/medicinedocs/en/d/Jh2934e/15.html>.)

6.2 The serious adverse event is associated with (check only one):

Cannabis-naïve patient – the first exposure to a cannabis product used for medical purposes

Non-naïve cannabis patient – no change in product or dose

Non-naïve cannabis patient – exposure to a new cannabis product or new batch

Non-naïve cannabis patient – exposure to a new dose of a cannabis product previously used

*If yes, exposure by:*  Dose increase  Dose decrease  New route of administration

Increased frequency of administration  Other, specify: \_\_\_\_\_

6.3 Did the reaction abate after use of the product was stopped?  Yes  No  Unknown

6.4 Did the reaction reappear after use of the product was reintroduced?  Yes  No  Unknown

**SECTION 7 – DETAILS OF CANNABIS EXPOSURE**

7.1 Was medical cannabis use:  Authorized (medically approved)  Unauthorized  Unknown

7.2 Was the product(s) acquired through (check all that apply):

Legal retailers (provincial/territorial authorized stores or websites)  Legally home grown/produced/prepared

Illegal sources  Unknown

*If legally acquired, product(s) information:* Product name (brand, strain, common name): \_\_\_\_\_

Licensed producer: \_\_\_\_\_

% cannabidiol (CBD): \_\_\_\_\_

% Δ 9-tetrahydrocannabinol (THC): \_\_\_\_\_

Lot/batch: \_\_\_\_\_

7.3 Route of exposure (check all that apply):

Ingestion  Inhalation  Other, specify: \_\_\_\_\_  Unknown

*If inhalation* (check all that apply):  Smoking  Vaping  Dabbing  Unknown

7.4 Product type:  Marijuana (whole/ground flowers and leaves)

Hashish

Orally ingestible cannabis oil

Hash oil (including butane hash oil known as BHO)

Dabs (shatter, wax, budder)

Cannabis tincture/extract

Cannabis edibles (in food, drink, or candy), specify: \_\_\_\_\_

Other, specify: \_\_\_\_\_

Unknown

7.5 Dose of cannabis in the 24 hours preceding the serious adverse event (e.g. grams, mg, mg/mL or number of joints):

Dose: \_\_\_\_\_  Unknown

I agree to be contacted by the CPSP for further information on this questionnaire.

I do not wish to be contacted by the CPSP for further information on this questionnaire.

#### SECTION 8 – REPORTING PHYSICIAN

First name \_\_\_\_\_ Surname \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ Province/territory \_\_\_\_\_ Postal code \_\_\_\_\_

Telephone number \_\_\_\_\_ Fax number \_\_\_\_\_

E-mail \_\_\_\_\_ Date completed \_\_\_\_\_

**Thank you for completing this form.**