Data on cannabis adverse reactions: 2022 annual report

Overview	2022-23 Annual report	2023 Annual report
2021 Annual report	2020 Annual report	Archived reports

Adverse reaction associated with cannabis reported to Health Canada between January 1, 2022 to December 31, 2022, with comparisons to the previous year (January 1, 2021 to December 31, 2021).

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Key highlights

In 2022, Health Canada received 1195 adverse reaction to cannabis reports (including duplicates, such as multiple reactions to the same product). Of these reports, 1 fatal case and 1 serious case were associated with legal cannabis products.

Out of the 1195 reports, 78 were unique cases associated with legal cannabis products.

Of the cases involving legal cannabis products:

- 1 fatal case involving a male
- 1 serious case involving a female (with pregnancy)
- Other involved cognitive complaints (such as memory loss), hallucinations, hypertension, psychosis, and dizziness.
- Most reported symptoms were consistent with those reported in previous years, including tachycardia, nausea and vomiting, hypertension, and psychosis.
- The most commonly reported adverse events were of cases involving legal cannabis products where possibly was suspected.

The most frequently reported adverse events across all cases involving legal cannabis products where possibly was suspected:

- Headache (n=8)
- Anxiety (n=6)
- Nausea (n=6)
- Dizziness (n=5)
- Drug ineffective (n=4)

In 2022, there were 1 "suspected case" of suspected drug abuse/misuse (SDA/SDM) that was reported as involving a legal cannabis product.

Most findings have remained consistent from 2021 to 2022. However, some changes were observed, namely:

- A decrease in the total number of cases (serious and non-serious)
- A decrease in the number of fatal cases involving legal cannabis products
- A decrease in the number of cases for seizures/poisonings reporting no symptoms
- A decrease in the number of cases reported, and, to some extent, the type of individuals involved in adverse reaction reports involving legal cannabis products

However, further years of data are required to confirm if these observations are part of a trend or simply fluctuations from year to year.

This report provides continuous to monitor, assess and report on adverse reactions associated with cannabis, and findings from clinical evaluations of serious and medically important cases reported as fatal and/or life-threatening, with cannabis, including risk communications and educational resources.

Introduction

This report describes the findings of the domestic case reports of adverse reactions associated with cannabis submitted to Health Canada's Canada Vigilance Adverse Reaction Online Database (Database) from January 1, 2022 to December 31, 2022. Canada's Database is part of Canada's Vigilance Program, which is a post-market surveillance program for products in Canada that has been in place since the coming into force of the Food and Drugs Act and Controlled Substances and Cannabis Act (CSCA).

The fourth annual data report presents a summary of all domestic case reports of adverse reactions associated with cannabis in Canada between January 1, 2022, and December 31, 2022, irrespective of being associated with a cannabis product or not, including those that were reported to Health Canada's Cannabis Tracking System.

The following categories are used to describe adverse reactions in a descriptive manner in Health Canada:

- **Fatal cannabis product** means cannabis v.0.1 of the Dried or Oil as defined in Schedule 4 to the Act, in a medicinal accepted dose and form for human consumption, which has been packaged and labelled for sale to a consumer at the retail level, that caused the death of a person.
  - Cannabis that is intended for an animal.
  - Cannabis that is intended for sale for use as a food or an edible cannabis.
  - Cannabis extract and cannabis concentrate.
- **An adverse reaction** is a noxious and unintended response to a cannabis or a cannabis accessory that contains cannabis.
- **A serious adverse reaction** is an unexpected adverse reaction that requires or prolongs hospitalization, causes persistent or significant disability or incapacity, or results in a congenital anomaly or birth defect.

For the purposes of this report, some reports involving suspected cannabis products (that is, identified by product brand name or lot/batch number) are classified as providing the intended use of the cannabis products as follows:

- **Legal cannabis product** means a product that is authorized for sale in accordance with the Cannabis Act and cannabis that can be produced in the cannabis medical market, intended for the medical use for the medical purposes, as defined in the "medical use of cannabis".
- **Illegal cannabis product** means a product that is not described, or mislabeled, or misleading the cannabis being used pursuant to a medical prescription provided by a health care practitioner or cases that are not in the medical market, or cannabis products that are not authorized for sale in accordance with the Cannabis Act and its regulations, and the definition of medical use within the Canadian Cannabis Survey. This is broader in scope than the definition of "medical use of cannabis" in the Cannabis Act and its regulations, and includes cannabis products that are not authorized for sale in accordance with the Cannabis Act and its regulations.

Adverse reaction reports are collected based on the Canada Vigilance Guidance. When adverse reaction case reports are submitted to Health Canada, they are coded using the Medical Dictionary for Regulatory Activities (MedDRA) and are assessed for seriousness, causality, and other factors. Information is then entered into Health Canada's Database. Adverse reaction reports may also originate from research studies, including:

- published case reports
- clinical trials, including Health Canada's Clinical Trials Database
- international human studies (including cannabis that fall outside of the definition of a clinical trial for cannabis, such as observational studies or expanded access programs)

While reports originating from clinical trials may be included in the Canada Vigilance Database, these reports are excluded from this report so they do not skew the overall data in the Medical Market of the Market. Therefore, number should be taken with the interpretation of these changes to results over the 4 reporting periods.

Health Canada's Database is a rich source of information, however, it has certain limitations such as:

- Confounded/masked by other factors
- Delays in reporting
- Lack of information on concomitant and temporal substances/ingredients

Reports may also be incomplete with respect to information such as the type of product, the product name, the product adverse reaction reports for other health products such as prescription and non-prescription drugs, or natural health products, and information on the product's dose, route of administration, and frequency.

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This report does not cover adverse reaction data associated with health products, including drugs containing cannabis, which are regulated under the Food and Drugs Act and the Regulations. A summary of adverse reaction reports associated with natural health products including Cannabis Sativa L. (Hemp) is also included in Health Canada's consolidated adverse reaction products including Cannabis Sativa L. (Hemp) report.

Considerations

Several factors must be considered when interpreting the adverse reaction data in this report.

Adverse reaction reports are spontaneously submitted to Health Canada and cannot be used to determine the incidence or prevalence of adverse reactions to cannabis in the general population.

Adverse reaction reports do not prove that a product caused the reported adverse reaction but have a regulatory obligation to report data to Health Canada and to assess the information to determine if the reaction is a serious or fatal adverse reaction by Science Fields to Health Canada to indicate their reports to voluntary. Therefore, the non-serious cases are less likely to be reported and thus only represented in the data.

Adverse reaction reports for cannabis products in relationship for:

- hospitals
- consumers
- health care professionals
- health care practitioners
- pharmacists and pharmacy assistants

Therefore, both serious and non-serious cases from these sources are likely underreported.

Adverse reaction reports for cannabis products in the medical market of products for medical purposes may be more motivated to report or even our medical product.

Several factors may influence the number and quality of case reports submitted to Health Canada such as:

- media attention
- regular for cannabis use
- consumer or patient medical history
- the "medical use of cannabis" in Canada
- awareness, recognition and ability to report
- nature of reports (spontaneous reports versus studies or other organized data collection systems)

Health Canada continues to monitor cannabis adverse reaction reports and to assess the information for signals of unknown adverse reactions, and any signal will be presented in this cannabis data report due to different factors and information from the Canada Vigilance database (for example, in the medical market for cannabis products, or medical report).

Health Canada's Database is a rich source of information, however, it has certain limitations such as: Confounded/masked by other factors, Delays in reporting, Lack of information on concomitant and temporal substances/ingredients, and Reporting of adverse reaction reports for cannabis products in relationship for: consumers, health care practitioners, and pharmacists.

Methodology

Cannabis products and cannabis

Adverse reaction associated with cannabis and a pharmacy

Figure 1: Reports associated with cannabis as a substance

Figure 1 – Text description

Cannabis

- This figure represents reports involving cannabis as a suspected substance that were submitted to Canada Vigilance database in 2022, including duplicates. Of the 1195 reports, 78 were unique cases associated with legal cannabis products.
- Reports are classified by internal reporting purposes (Health Canada Regulatory Operations and Regulation) that using legal cannabis products (used for either for medical or non-medical purposes) 51 classification use case. Cases that are not in the medical market (illegal cannabis products, or cannabis products that are not authorized for sale in accordance with the Cannabis Act and its regulations) are classified as "illegal cannabis".
- Under the Cannabis Act and Regulations which provides a legal pathway for people who are a maximum of 4 cannabis plants for personal use, Health Canada's Cannabis Tracking System (CTS) is used to track the sale of legal cannabis. Cases that are not in the medical market (illegal cannabis) involving homicide and suicide are excluded from this report to protect the identity of individuals.

A total of 198 reports (Cannabis Adjustment 77 associated with cannabis as a suspect substance were submitted to Health Canada between January 1, 2022, and December 31, 2022, which is the number of reports received by Health Canada and entered into the database during the reporting period. Of these reports, 78 were unique cases associated with legal cannabis products, 48% (n=37) and non-medical purposes 51% (n=40). Of the reports involving unknown or illegal cannabis, 24% (n=48) were non-medical purposes, 51% (n=1) medical purposes, and 25% (n=1) unknown purposes. Of the 1195 reports, 1 report involving a male (n=1) received additional suspect cannabis products (illegal cannabis) and 1 report involving a female (n=1) received a suspect cannabis, a derivative from 28 to n. 1 report included the contamination of hashish, from an unknown source, into the medical market.

Report of vaping associated lung illness (VALI)

Health Canada's Database contains 1 report of vaping associated lung illness reported to the Canada Vigilance database in 2022. However, this case was initially reported to Health Canada in 2021 and was included in the 2021 Annual report. Of the 1 reported adverse reaction, 1 report involved a male (n=1) and 1 report involved a female (n=1). Of the reports, 1 report involved the consumption of cannabis, from an unknown source, into the medical market.

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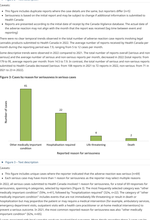

Number of reports
Medical purposes
Non-medical purposes
Unknown
Other medical purposes
Unknown
Other medical purposes
Medical purposes
Non-medical purposes
Unknown
Other medical purposes
Medical purposes
Non-medical purposes
Unknown
Other medical purposes
Medical purposes
Non-

- Figure 9 – Text description

Cannabis

- This chart was developed by Health Canada through manual categorization of cases according to their sub-class of cannabis product.
- Cases may have multiple suspected cannabis product reported across different sub-classes of cannabis. For this reason, the total number for the table according to class of suspect products by sub-class are not equivalent to the total number of unique cases.
- Cannabis products were reported in the following sub-classes: fresh/dry including oil liquids or drops, softgels, capsules or tablets, sublingual sprays, sublingual strips or tablets, concentrated extracts (hash, wax, resin, resin or vaping liquids. Other cannabis includes whole dried flower, milled flower, and pre-rolls. Edibles include food products and beverages. Topicals include creams, ointments, and lotions.
- Dual or Gray (ingestible) are listed separately from ingestible products because these products are marketed outside of non-medical use that is inside the record that may absorb directly into the bloodstream.

Adverse drug reaction cannabis were reported in the following sub-classes: fresh/dry including oil liquids or drops (most reported) followed by adverse reaction cases, along with dried cannabis. Within the category of cannabis extracts, ingestible oils is higher than other cannabis extracts. Cannabis extracts (hash, wax, resin, resin or vaping liquids) are reported in similar frequencies. Approximately 85% (n=2) of the 2 of adverse reaction cases with vaping cannabis extracts were reported. Ingestible oil softgels/capsules from representative (2%) (n=12). This is generally consistent with observations from 2021, which reported 2% (n=2) of adverse reaction cases with ingestible oil softgels/capsules. Dual or Gray (ingestible) cases (n=3) represent 50% (n=3) of adverse reaction cases with ingestible oil softgels/capsules.

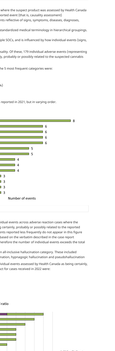
Inconsistent with 2021, cannabis extracts were the most frequently reported class across all age groups (under 18 years, 18 to 34 years and 35 years or older). While distinguishing cannabis extracts, pooling ingestible and gray (n=3) and 18 to 34 years) were most frequently involved in adverse reaction cases with vaping liquids, and sprays and cannabis topicals, and ingestible oil softgels/capsules. Cannabis extracts (hash, wax, resin, resin or vaping liquids) were reported in similar frequencies in the 35 years. This is generally consistent with data from 2021 where cannabis extracts (hash, wax, resin, resin or vaping liquids) were reported in adverse reaction cases with vaping liquids and oil sprays, while other cannabis extracts (hash, wax, resin, resin or vaping liquids) frequently involved adverse reaction cases with ingestible oil and topical cannabis products.

Some consumers or patients may preferentially select ingestible cannabis oil products for 1 or more reasons such as:

- for duration of effect
- to avoid inhaling cannabis
- for ease of administration
- for the ability to dose or titrate a specific measured dose
- other reasons

In addition, adverse effects in terms of age may be more sensitive to cannabis and have a higher risk of experiencing adverse reactions. This is especially true when taking cannabis products for medical purposes or any other health problem, which may be more sensitive to cannabis and have a higher risk of experiencing adverse reactions. Cannabis products are not recommended.

Figure 10: Breakdown of reactions by system organ class (SOC)



- Figure 10 – Text description

Cannabis

- The figure shows SOCs across all adverse reaction cases where the suspect product was assessed by Health Canada as being certainly, probably or possibly related to the reported event (that is, causality assessment).
- Cases could have multiple SOCs reported, including psychiatric disorders, nervous system disorders, diagnoses, investigations, and product issues.
- Events are coded according to MedDRA, which provides standardized medical terminology in hierarchical groupings, from broad to specific terms.
- 1 adverse reaction case may be represented across multiple SOCs, and the number of events (for example, nervous system disorders, or diagnoses) are reported across SOCs.

Health Canada received a total of 10 adverse reports for causality. Of these, 19 individual adverse events (representing 117 unique event categories) were assessed as being certainly, probably or possibly related to the suspected cannabis product, and were included in this analysis.

The most frequent SOCs (number of events) were:

- psychiatric disorders (26%)
- nervous system disorders (17%)
- general disorders and administration site conditions (14%)
- respiratory, thoracic and mediastinal disorders (12%)
- gastrointestinal disorders (11%)

These top 5 SOCs for 2022 are consistent with the top 5 SOCs reported in 2021, but in varying order.

Figure 11: Frequency of individual events

- Figure 11 – Text description

Cannabis

- This figure focuses on the most frequently reported individual events across adverse reaction cases where the suspect product was assessed by Health Canada as being certainly, probably or possibly related to the reported event (that is, causality assessment). Cases could have multiple events reported, including headache, seizure, hallucination, dysgeusia, drug ineffective, anxiety, drug hyperkinesia, dysphagia, dysphonia, dyspnea, dyspepsia, diarrhea, dizziness, hypoaesthesia, nausea, vomiting, product quality issue, product substitution issue, vertigo, condition aggravated, euphoric mood.
- Events are coded according to MedDRA, which provides standardized medical terminology in hierarchical groupings, from broad to specific terms.
- 1 adverse reaction case may be represented across multiple SOCs, and the number of events (for example, headache, seizure, hallucination, dysgeusia) are reported across SOCs.

Health Canada received a total of 10 adverse reports for causality. Of these, 19 individual adverse events (representing 117 unique event categories) were assessed as being certainly, probably or possibly related to the suspected cannabis product, and were included in this analysis.

The most frequent individual events (number of events) were:

- headache (11%)
- seizure (10%)
- hallucination (10%)
- dysgeusia (10%)
- drug ineffective (10%)
- anxiety (10%)
- drug hyperkinesia (10%)

Figure 12: Frequency of individual events by cannabinoid ratio

- Figure 12 – Text description

Cannabis

- This figure focuses on the most frequently reported individual events across adverse reaction cases after stratification by cannabinoid ratio, where the suspect product was assessed by Health Canada as being certainly, probably or possibly related to the reported event (that is, causality assessment). This figure excludes cases without information on cannabinoid ratio. Cases could have multiple events reported, including hallucination, dysgeusia, seizure, dysphagia, other than observed in Figure 11. Other events were reported during the reporting period but do not appear in this figure.
- Cannabis products were reported by Health Canada by cannabinoid ratio suspect cannabis product to a cannabinoid ratio based on available information and assigning of individual events within a class of reported suspect cannabis products and their cannabinoid ratio (weighted equally for all events). Therefore, this may over-estimate the correlation between cannabinoid ratio and individual events.
- The category "Unknown" is considered a THC:CBD ratio between 1:1 and 1:2.

Cannabis products with a THC:CBD ratio greater than 1:1 were reported in a greater number of a greater THC to CBD ratio (that is, a THC:CBD ratio greater than 1:1) compared to products containing a greater CBD to THC ratio (that is, a CBD:THC ratio greater than 1:1). In Highlighted in Figure 12, unknown individual adverse events were more frequently reported with products containing a greater THC to CBD ratio, while events were more frequently reported with products containing a greater CBD to THC ratio.

For example, the following were more frequently reported with products containing a greater ratio of THC to CBD:

- anxiety
- seizure
- vomiting
- nausea
- dysgeusia
- headache
- product quality issue
- product substitution issue

Whereas the following were more frequently reported with products containing a greater ratio of CBD relative to THC:

- malaise
- diarrhea
- hallucination
- drug ineffective
- condition aggravated

These are reported events only and other factors may be contributing to these events including:

- dosage
- route of administration
- other cannabinoids or constituents of effects of cannabis and cannabinoids
- prior exposure to cannabis (for example, cannabis naive versus experienced)
- reporting factors such as motivation to report, risk tolerance or awareness of reporting
- the age and status of patients (including pre-existing health conditions and use of concomitant medications)

However, the variety or dose among commonly or preferentially used products in the current market of the cannabis class.

Sex and Gender Based Analysis Plus of 2022 Adverse Reaction Data

Figure 13 – SEX: Males vs. Females

- Figure 13 – Text description

A total of 52 adverse reaction cases included a designation for sex in 2022. Of these cases 59% (n=31) involved males, 41% (n=21) involved females. Of the 31 male cases, 6 (19%) were under 18 years, 25 (81%) were adult (18 years and older). Of the 21 cannabis for medical purposes (n=21 each). Non-serious cases and for non-medical purposes more frequently involved males than females.

Females involved in adverse reaction cases associated with cannabis products were generally older than males. When age was reported (n=19), the average age of females was 41.9 years (95% CI: 34.1-49.6) and 38.6 years for males (95% CI: 32.1-45.1).

Figure 14 – SEX plus Cannabis by age group (years)

- Figure 14 – Text description

Adverse reactions cases involving ingestible cannabis extracts in liquid format (bottled only), inhalable liquid extracts (vaped), oral sprays and dried cannabis more frequently involved males than females. Conversely, edibles (beverages and food products) and topicals more frequently involved females.

Adverse reactions involving ingestible cannabis extracts in liquid format (bottled only), inhalable liquid extracts (vaped), oral sprays and dried cannabis more frequently involved males than females. Conversely, edibles (beverages and food products) and topicals more frequently involved females.

Table 1 – Top individual events reported by sex

Females	Males
Hallucination (11.1%)	Headache (11.1%)
Diarrhoea (n=9)	Drug ineffective (n=8)
Seizure (n=7)	Hallucination (7.1%)

1 Including visual, auditory, mixed, hypnagogic and pseudohallucinations.

Clinical evaluation of serious and medically important cases

Summary of serious and medically important adverse reactions

All individual events within an adverse reaction case that is reported as serious to Health Canada are assessed for causality. Of the 10 adverse reaction cases with a serious outcome, 19 individual events were assessed as being certainly, probably or possibly related to the suspected cannabis product. Table 2 provides information on the causal association between events and exposure to the cannabis products. Causality assessment is a clinical investigation of cases and is a routine practice in pharmacovigilance to determine the likelihood of association between the suspect product and the adverse reactions. This practice supports the identification of potential safety concerns that may require further investigation or actions by the regulatory authority to protect the health of Canadians.

Table 2 – Causality assessment of serious cases

Causality Assigned	Number of events
Certain	0
Probable	0
Possible	12
Unlikely	41
Unassessable	65
Total	118

Overall, most events were assigned a causality of "Possible" (50%, n=12), meaning there was a reasonable possibility of a causal relationship between the suspect cannabis product and the reported event. Of the remainder of cases, 41 were found to be rated as "Unlikely" (no reasonable evidence to a causal relationship).

2 events were assigned a causality of "Certain" (2%), for which a stringent level of evidence is required, including both laboratory and medical evidence to be met, the cause must be very clear otherwise alternatives must be ruled out.

The 2 events assigned a causality of "Certain" (n=2 cases) all involved psychomotor or administration issues, namely:

1. seizure (suspected administration issue)
2. serious product administration error
3. product administration error

Each case involved a single cannabis extract product for ingestion (softgel capsules, oil), oils, n=12, no n=2 suspect products were reported. All individuals had pre-existing medical conditions, reported use of concomitant health products and were reported as being administered cannabis medical purposes (indication of use included epilepsy, sleep disorder, cancer palliative care, and pain).

There were 6 events assigned a causality of "Probable" (5%), meaning there was sufficient information to judge that the cannabis product probably contributed to the adverse reaction and the contribution of other factors was considered to be unlikely.

The 6 events assigned a causality of "Probable" represented 4 cases.

- 1 cases associated with legal cannabis extract products for ingestion (softgel capsules, n=1, oil, n=3, n=1 product was reported).
- 1 involved multiple suspected products (oil and vape)

Among these cases, 3 out of 4 reported cannabis as a sole suspect product, meaning that no other health products were reported as concomitant. Of the remaining cases, 1 reported use of concomitant health products and 1 reported use for self-reported medical purposes (indications of use included anxiety, pain or epilepsy). All but 1 case reported use of concomitant health products.

There were 41 events assigned a causality of "Unlikely", meaning there was sufficient information to establish a causal association between the cannabis product and the reported adverse reaction.

This report represents the 41 cases identified at the end of 2022 and by comparing the cannabis product was judged to not play a causative role in the reported adverse reaction (other probable factors identified).

Important Identified risks during the reporting period

During this reporting period, no serious or medically important cases were classified as having new important identified risks associated with the cannabis product. Of the remaining cases, 65 were found to be rated as "Unassessable" (55%), meaning that the cause could not be determined due to insufficient information for a judge reason.

Most serious or medically important cases with "Probable" causality were considered to involve known identified risks. That is, the risk is already been identified and incorporated into Health Canada's Information for Health Care Professionals document (last updated: Spring 2018). These include:

- Psychiatric disorders (for example, anxiety, hallucinations)
- Psychiatric disorders (for example, anxiety, hallucinations)
- Respiratory tract infections (for example, throat irritation)
- Cardiovascular reactions (for example, arrest/fibrillation, palpitations, tachycardia)
- Hepatobiliary (allergic reactions (for example, symptoms (hypersensitivity reactions)

Important products during the reporting period

2 Important potential risks were observed in adverse reaction data with cannabis products during this reporting period. Information on these potential risks is available in the current version of the Information for Health Canada document, and in the current version of the product monographs for approved cannabis products.

Risk of new product of interest in individuals without pre-existing psychiatric disorder with the use of cannabis products (THC, CBD, balanced)

While there is some research to suggest that cannabis, specifically CBD, may be helpful in the treatment of secure psychiatric disorders, there is also evidence that cannabis, specifically THC, may be associated with psychiatric disorders such as psychosis, and other adverse reactions. Cannabis products are not recommended for use in individuals without pre-existing psychiatric. Health Canada initiated in 2022 a preliminary signal assessment to assess the potential risk of new onset secure in healthy individuals consuming increased cannabis products (THC, CBD, balanced). A total of 10 adverse reaction reports were identified in which consumption or secure was reported and assessed as being "probably" (n=5) or "possibly" (n=5) related to the cannabis product. Of the 10 reports, 6 were for cannabis products with a high ratio of THC, 3 were balanced and one was a product with a high ratio of CBD. Most individuals were using cannabis for medical purposes and, therefore, had pre-existing conditions (other than secure disorder or convulsion). However, most reported no pre-existing psychiatric conditions and reported use of other medications. Based on the results of the preliminary signal assessment, a full signal assessment (signal assessment) will be conducted, which will include a review of domestic and foreign data, as well as evidence from the published literature to determine whether this important potential risk warrants any risk mitigation.

Risk of synthetic with the use of cannabis products (THC, CBD, balanced)

This signal assessment was initiated in the end of 2022 and is currently being assessed by Health Canada.

Ongoing monitoring of safety signals

Health Canada will continue to monitor for any new literature and adverse reaction reports for the following risks:

- hypoglycemic events amongst cannabis users
- cannabinoid interactions with other commonly prescribed commonly products
- cannabis products for the treatment of anxiety, seizures, hypnosis, sleep disorder, neuromuscular, bronchospasm
- blood clotting in individuals that concurrently use cannabis products and estrogen containing combined oral contraceptives

Fatal cases during the reporting period

During this reporting period, Health Canada conducted a comprehensive assessment on 2 fatal cases involving cannabis products for medical purposes.

- Case 1
- Case 2

Note to readers

Adverse reaction cases with cannabis submitted to Health Canada are received and entered into the Canada Vigilance Adverse Reaction Online Database (Health Product Directorate (HPD) and Marketed Health Products Directorate (MHPD) collects, monitors and analyzes adverse reactions submitted to the Canada Vigilance database, amongst other activities, and takes action where necessary to ensure safety of Canadians. The Controlled Substances and Cannabis Branch (CSCB) is responsible for the monitoring, detection, prioritization, evaluation and aggregate reporting of adverse reactions associated with cannabis products for medical purposes.

Voluntary reports from the public may be received as a "serious" or "non-serious" adverse reaction. Health Canada will change the primaire form as electronic file or mailing to Health Canada. Mandatory reports are submitted by licence holders in accordance with the Food and Drugs Regulations (C.R.C., c. 870) and Marketed Health Products Regulations (SOR/2014-230). Suspected "serious" adverse reactions are required to be submitted to Health Canada within 15 days of receipt of the Canada Vigilance database (specific license must be met). Cannabis complaints and product quality issues may also be relied on the Cannabis complaints system for Health Canada. Incidents involving cannabis products (for example, mechanical, physical or electrical issue in failure of a cannabis substance and associated injuries) can be reported via the Consumer Product Safety Reporting Form or by contacting the Canada Consumer Product Safety Bureau.

Suspected adverse reaction cases are coded in the following manner:

1. Case reports are translated into electronic data into the Canada Vigilance database. All individual events are coded using the MedDRA, which is standard international medical terminology developed by the International Conference of Technical Requirements for Pharmaceuticals for Human Use as an international set of standardized medical terms to facilitate the sharing of regulatory information internationally.
2. Case reports involving cannabis are in combination with other products, Health Canada assigns a "suspect" or "concomitant" ingredient level, irrespective of the identity of the cannabis product (legal, illegal, unspecified, unidentified). Suspect products are those products that are considered to be the most probable cause of the adverse reaction. Concomitant products are those products that are not considered to be the most probable cause of the adverse reaction but are considered to be used for non-medical purposes (non-medical cannabis), based on the information in the report. Cannabis can be used for medical purposes, but it is not known if the product was used for medical purposes in the case of a non-medical therapeutic purpose or indication, without intention of a medical authorization (illegal). If there is no reported reason for use provided in the report, minimal details or intended use for non-medical purposes, the report is considered to be non-medical.
3. Case reports are coded as serious as reported if at least 1 criterion for seriousness is selected:
   - death
   - life-threatening
   - admitted to the hospital
   - prolonged hospitalization
   - disability
   - birth defect
   - other medically important condition may also be selected by the reporter
4. According to international pharmacovigilance guidelines (ICH guideline E2D), 15 medically important conditions may also be considered serious under certain circumstances and therefore are an option to select when reporting an adverse reaction. Health Canada has adopted the following medical conditions as "other medically important conditions" (these cases technically fall under the regulatory definition of serious adverse reaction under the Food and Drugs Regulations).

Health Canada conducts routine monitoring, detection, assessment and associated activities for all cannabis adverse reaction reports, which involves:

- Health Canada will review case reports to ensure they are:
  - coded appropriately according to MedDRA
  - classified as either cannabis for medical or non-medical purposes (illegal unspecified, unidentified)
- Case reports involving cannabis are in combination with other products, Health Canada assigns a "suspect" or "concomitant" ingredient level, irrespective of the identity of the cannabis product (legal, illegal, unspecified, unidentified). Suspect products are those products that are considered to be the most probable cause of the adverse reaction. Concomitant products are those products that are not considered to be the most probable cause of the adverse reaction but are considered to be used for non-medical purposes (non-medical cannabis), based on the information in the report. Cannabis can be used for medical purposes, but it is not known if the product was used for medical purposes in the case of a non-medical therapeutic purpose or indication, without intention of a medical authorization (illegal). If there is no reported reason for use provided in the report, minimal details or intended use for non-medical purposes, the report is considered to be non-medical.
- Case reports are coded as serious as reported if at least 1 criterion for seriousness is selected:
  - death
  - life-threatening
  - admitted to the hospital
  - prolonged hospitalization
  - disability
  - birth defect
  - other medically important condition may also be selected by the reporter
- According to international pharmacovigilance guidelines (ICH guideline E2D), 15 medically important conditions may also be considered serious under certain circumstances and therefore are an option to select when reporting an adverse reaction. Health Canada has adopted the following medical conditions as "other medically important conditions" (these cases technically fall under the regulatory definition of serious adverse reaction under the Food and Drugs Regulations).

Health Canada conducts routine monitoring, detection, assessment and associated activities for all cannabis adverse reaction reports, which involves:

- Health Canada will review case reports to ensure they are:
  - coded appropriately according to MedDRA
  - classified as either cannabis for medical or non-medical purposes (illegal unspecified, unidentified)
- Case reports involving cannabis are in combination with other products, Health Canada assigns a "suspect" or "concomitant" ingredient level, irrespective of the identity of the cannabis product (legal, illegal, unspecified, unidentified). Suspect products are those products that are considered to be the most probable cause of the adverse reaction. Concomitant products are those products that are not considered to be the most probable cause of the adverse reaction but are considered to be used for non-medical purposes (non-medical cannabis), based on the information in the report. Cannabis can be used for medical purposes, but it is not known if the product was used for medical purposes in the case of a non-medical therapeutic purpose or indication, without intention of a medical authorization (illegal). If there is no reported reason for use provided in the report, minimal details or intended use for non-medical purposes, the report is considered to be non-medical.
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Reporting an adverse reaction involving a cannabis product

Health Canada encourages adverse reactions to be reported to Health Canada by completing a Canada Vigilance adverse reaction form and sending it by mail or fax. Health Canada does not provide medical advice or treatment recommendations for specific medical problems. More information can be found in the Canada Vigilance adverse reporting guide for licence holders.

Consumers and health care professionals are encouraged to report any adverse reaction to a cannabis product directly to Health Canada. Consumers and health care practitioners may also send a report to the licence holder of the product.

Report an adverse reaction from Cannabis

Contact us

Any questions or comments on this report, including any requests for the data used to support this report, should be directed to cannabis_sex-gender_health@hc-sc.gc.ca.

Glossary

1) Under the Cannabis Act and Regulations authors are allowed to legally grow up to a maximum of 4 cannabis plants for personal use. This is in addition to any plants that may be authorized for personal and designated person production. Under the Cannabis Act and Regulations, it is illegal to sell cannabis plants or seeds to anyone outnumbering licence grants for non-medical purposes may be issued for the cultivation and organization of individual processes or territory.

2) Under the Cannabis Act and Regulations adults are allowed to make products at home for personal consumption using cannabis that they have given legally or using cannabis that they obtained from other adult Canadians.

3) As per paragraph 14(b.1)(ii) of the Cannabis Regulations, all adverse reactions, including non-serious adverse reactions, must be maintained in an annual summary report by the licence holder, which can be requested by Health Canada.

4. Duplicate cases may exist if an adverse reaction report about the same adverse reaction event was received from different reporters (for example, from a health professional, consumer, licence holder, and/or manufacturer).

5) World Health Organization (2012). Safety monitoring of medicinal products. Reporting system for the general public. available from: https://apps.who.int/medicinedocs/en/d/Jh2988e/5.1.1.1.html

6) European Medicines Agency (2015). Guideline on good pharmacovigilance practices (GVP). Annex I – Definitions (Rev 4). available from: https://www.ema.europa.eu/en/human-regulatory/overarching/pharmacovigilance/ema-annexes-definitions-rev-4-en.pdf

7) European Medicines Agency (2006). ICH Topic E2D: Post Approval Safety Data Management Step 5. Definitions and reporting requirements for spontaneous post-approval pharmacovigilance information. Technical requirements registration pharmaceuticals human use. pm 5.pdf

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