



DATA ON CANNABIS ADVERSE REACTIONS: 2023 ANNUAL REPORT

**Adverse reactions associated with cannabis
reported to Health Canada between January 1,
2023 to December 31, 2023**



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To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

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KEY HIGHLIGHTS

In 2023, Health Canada received 128 reports¹ of adverse reaction reports (including duplicates, such as multiple reporters of the same adverse reaction) associated with cannabis as a suspected substance.

Out of the 128 reports, 56 were unique cases² associated with legal cannabis products.

Of the 56 unique cases involving legal cannabis products:

- 45% involved females and 39% involved males
- 59% involved cannabis used for medical purposes (self-reported)
- 64% involved cannabis extracts
- 27% of cases involved adults aged 18 to 44 years and 23% were missing age-related information
- 52% of cases were reported as serious, with other (medically important condition) as the most frequently reported reason for seriousness

207 adverse events reported across the 56 unique cases were assessed for causality; 96 were deemed to be certainly, probably or possibly related to the suspect cannabis product(s). The most frequently reported adverse events across all cases involving legal cannabis products where a causal relationship was determined included:

- headache (n=7)
- vomiting (n=5)
- dizziness (n=5)
- agitation (n=3)
- loss of consciousness (n=3)
- anxiety (n=3)

In 2023, there were no suspected cases of vaping-associated lung injury (VALI).

Most findings have remained consistent from 2022 to 2023, however, some changes were observed, namely:

- a decrease in the total number of cases (serious and non-serious)
- a shift in some of the reasons for seriousness being selected by reporters
- the types of adverse events reported, and, in some instances, the type of individuals involved in adverse reaction cases (for example, the distribution of sex)

¹ The term “report” indicates the inclusion of report duplicates where the case details are the same, but the reporters differ (for example, submission of the same case in separate reports by both a licence holder and a consumer). Within this data report, this terminology is used where the indicator being discussed is dependent on information provided in each individual report (for example, type of reporter, date of submission, etc.).

² The term “case” indicates that duplicate reports have been removed. Within this data report, this terminology is used where the indicator being discussed is not dependent on information provided in each individual report (for example, seriousness, reason for seriousness, demographic information, reported events, etc.). Most sections and figures will refer to cases instead of reports.

Health Canada continues to monitor, assess and report on adverse reactions associated with cannabis, and findings continue to be used to prepare evidence-based educational materials on health and safety risks 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 database and analyzed by the Office of Cannabis Science and Surveillance of the Controlled Substances and Cannabis Branch in Health Canada. This work forms part of the Vigilance Framework for Cannabis that has been in place since the coming into force of the *Cannabis Act* and *Cannabis Regulations* (October 17, 2018).

This annual data report presents a summary of all domestic case reports of adverse reactions submitted to Health Canada between January 1, 2023, and December 31, 2023, suspected of being associated with a cannabis product as defined under the *Cannabis Act* or its Regulations, intended for human consumption.

For the purposes of this report:

- A **legal cannabis product** means cannabis of 1 of the classes set out in [Schedule 4 to the Act](#), or a cannabis accessory that contains such cannabis, after it has been packaged and labelled for sale to a consumer at the retail level. It does not include:
 - cannabis that is intended for an animal
 - health products containing cannabis or for use with cannabis
 - a cannabis accessory that contains cannabis that is intended for an animal
- An **adverse reaction** is a noxious and unintended response to cannabis or a cannabis accessory that contains cannabis
- A **serious adverse reaction** is an adverse reaction that requires inpatient hospitalization or a prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death

Licence holders who sell or distribute a cannabis product must provide Health Canada with a detailed report must within 15 days of becoming aware of a serious adverse reaction to the cannabis product. This report must contain all information in their possession associated with the use of the cannabis product by the individual who experienced the reaction.

The following groups may also submit adverse reaction reports on a voluntary basis to Health Canada:

- patients
- consumers
- health care practitioners
- medical cannabis clinics
- other reporters such as provincial and territorial authorized retailers

Reports may also be received from market authorization holders of licensed health products that submit adverse reaction reports for other suspect health products (such as prescription or non-prescription drugs, or natural health products) in which cannabis is also identified as a co-suspect product.

Adverse reaction reports with cannabis may involve cannabis that is:

- from an illegal source

- a legal cannabis product
- cultivated³ or produced⁴ in the home for personal use
- undefined (cannabis as a substance not otherwise specified)

For the purposes of this report, case reports involving a legal cannabis product (that is, identifiable by legal product brand name or legal licence holder) are classified according to the intended use of the cannabis products as follows:

- **Cannabis use for non-medical purposes:** If there is no reported medical or therapeutic indication or reason for use provided in the adverse reaction report, if the report contains minimal details, or the intended use of cannabis is for non-medical purposes, the case is classified as “non-medical use of cannabis”.
- **Cannabis use for medical purposes:** This includes cases described as involving the cannabis being used pursuant to a medical authorization document provided by a health care practitioner, or cases that report the use of the cannabis for a medical or therapeutic purpose, without mention of a medical authorization document. This definition aligns with the definition of medical use of cannabis within the [Canadian Cannabis Survey](#). This is broader in scope than the definition of cannabis use for medical purposes under the *Cannabis Regulations* which only includes cannabis obtained with a medical authorization document from a health care practitioner.

Adverse reaction reports are collected and housed in the [Canada Vigilance database](#). Most adverse reaction case reports submitted to Health Canada with cannabis are reported spontaneously by consumers, patients, health care practitioners or by licence holders (referred to as market authorization holders [MAH] in the Canada Vigilance database). However, reports may also originate from research studies, including:

- published case studies
- observational studies (non-interventional, real-world)
- interventional human studies involving cannabis that fall outside of the definition of a clinical trial (for example, non-therapeutic research on cannabis studies)
- other organized data collection systems (for example, patient registries)

While reports originating from clinical trials may be included in the broader Canada Vigilance dataset, these reports are excluded from this data report as they fall under the purview of the Clinical Trials Framework under the [Food and Drugs Act](#) and Regulations.

Health Canada conducts near-time monitoring, detection, and assessment of cases of adverse reactions involving cannabis products as part of the Vigilance Framework for Cannabis. Health Canada also monitors cases involving cannabis as a substance for broader issues of public health importance such as:

- vaping-associated lung illness
- cases involving pediatric populations

³ Under the *Cannabis Act* and Regulations adults 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 production for medical purposes, which can vary across the provinces and territories. However, rules surrounding home growing for non-medical purposes may vary based on the rules and regulations of individual provinces or territories.

⁴ Under the *Cannabis Act* and Regulations adults are allowed to make products at home for personal consumption using cannabis that they have grown legally or using cannabis that they obtained from other legal sources.

- other potential emerging safety issues

The purpose of this report is to provide a brief summary of adverse reaction reports involving cannabis, as well as a descriptive analysis of adverse reaction data associated with legal cannabis products, submitted to Health Canada between January 1, 2023, and December 31, 2023.

In addition to the descriptive analysis of cases from 2023, comparisons to the previous reporting period (January 1, 2022, to December 31, 2022) have been made, where appropriate. These comparisons are largely descriptive, and differences have not been tested for statistical significance in most cases due to the limited nature of the data. Therefore, caution should be taken when interpreting changes in results over the 2 reporting periods.

Data for other reporting periods, including trends across periods, are also publicly available:

- [Cannabis-related side effects: Key findings](#)
- [Data on cannabis adverse reactions](#)

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 its Regulations.

Considerations

Certain caveats should be considered when interpreting the adverse reaction data in this report.

The inclusion of a particular report in the database does not necessarily mean that there is a causal relationship between the reported cannabis products and adverse events. Additional scientific investigations are required to establish a cause-and-effect relationship.

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

Serious adverse reactions have a greater representation in this dataset as licence holders have a regulatory obligation to report these to Health Canada under section 248.1 of the *Cannabis Regulations*. The submission of non-serious adverse reactions by licence holders to Health Canada as individual case reports is voluntary,⁵ therefore, the non-serious cases are likely underreported and likely underrepresented in this dataset.

Reporting of adverse reactions for cannabis products is voluntary for:

- hospitals
- consumers
- medical cannabis clinics
- health care practitioners
- provincial and territorial retailers

⁵ As per paragraph 248.1(1)(b) 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.

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

Individuals experiencing serious outcomes or using cannabis products for medical purposes may be more motivated to report or seek out medical attention.

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

- media coverage
- reason for cannabis use
- consumer or patient medical history
- length of time a product is on the market
- awareness, motivation and ability to report
- nature of reports (spontaneous reports versus studies or other organized data-collection systems)

This report includes information on cannabis for medical and non-medical purposes; however, the number of cases elsewhere may not directly align with what is presented in this current data report due to different dates of extraction from the Canada Vigilance database (for example, in the [adverse reactions to health products - annual report 2022](#)).

Case reports involving cannabis products for self-reported medical and non-medical purposes from the legal marketplace and regulated under the *Cannabis Act* and its Regulations form the basis for the remaining portions of this Annual Report.

ADVERSE REACTIONS WITH CANNABIS

Adverse reactions associated with cannabis as a substance

Figure 1: Reports associated with cannabis as a substance

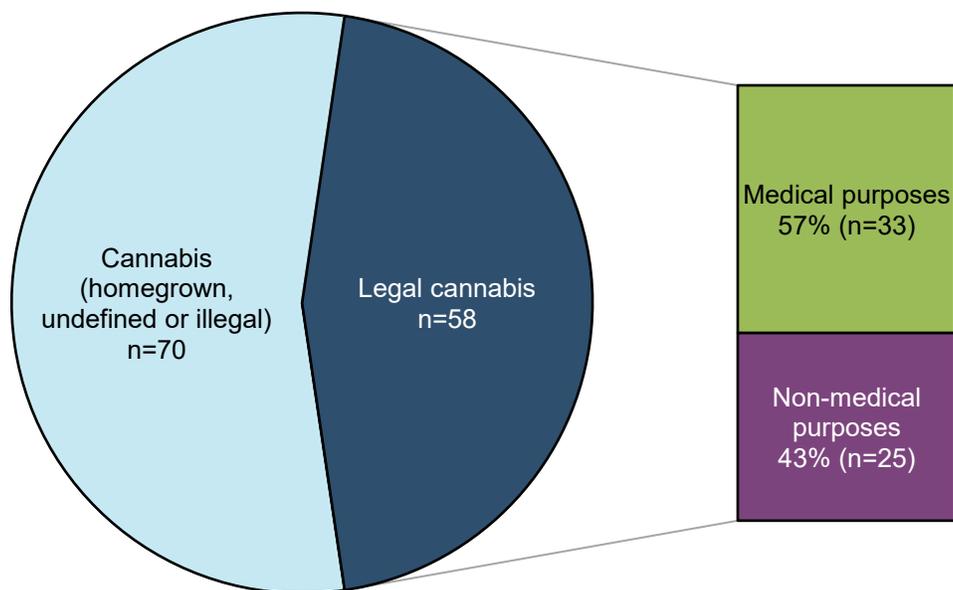


Figure 1 – Text description

	Number of reports	Proportion (%)
Cannabis (homegrown, undefined or illegal)	70	55
Legal cannabis products- Medical purposes	33	26
Legal cannabis products – Non-medical purposes	25	20
Total	128	100

Caveats:

- This figure represents all reports involving cannabis as a suspected substance that were submitted to Canada Vigilance database in 2023, including duplicate reports where the case details are the same, but reporters differ (n=23)
- Reports are classified for internal reporting purposes within Canada Vigilance depending on whether they report using legal cannabis products used for either for medical or non-medical purposes (1 classification per case). Cases that do not involve cannabis products from legal sources are not assigned a classification and remain classified as cannabis as a substance only (undefined or illegal cannabis)
- Under the *Cannabis Act* and Regulations adults are allowed to legally grow up to a maximum of 4 cannabis plants for personal use. However, this cannabis cannot legally be packaged and labeled for sale at the retail level. Therefore, adverse reaction reports involving homegrown cannabis are kept separate from reports involving legal cannabis products

A total of 128 reports (includes duplicates⁶) associated with cannabis as a suspect substance were submitted to Health Canada between January 1, 2023, and December 31, 2023.

- 55% (70/128 reports) involved cannabis from an unknown or illegal source, where the report cites 'cannabis' or 'marijuana' without specific details
- 41% (29/128 reports) involved additional co-suspect substances or health products (for example, polysubstance or polypharmacy reports) in addition to cannabis, an increase from 19% in 2022
- 45% (58/128 reports) involved legal cannabis products, of which most were self-reported as being used for medical purposes (57%, 33/128 reports)
- No reports involving homegrown cannabis were reported in 2023

Report of vaping-associated lung illness (VALI)

Health Canada continues to monitor for reports of suspected VALI.

There were no suspected reports of VALI involving cannabis reported to the Canada Vigilance database in 2023.

For more information on VALI in Canada:

- [Vaping-associated lung illness](#)
- [Public Health Notice: Outbreak of Vaping-Associated Lung Illness \(VALI\) from September 2019 to August 2021 in Canada](#)

Reports involving the pediatric population (under 18 years)

In 2023, there were 44 reports of adverse reactions to cannabis involving the pediatric population (aged under 18 years), an increase from 39 reports in 2022:

- 52% (23/44 reports) involved cannabis from an unknown source
- 43% (19/44 reports) involved cannabis from an identifiable or suspected illegal source
- 4.5% (2/44 reports) involved legal cannabis products

In terms of route of administration:

- 41% (18/44 reports) involved cannabis consumed orally, mostly in an edible format (14/18 reports)
- 27% (12/44 reports) involved inhalation as a route of administration, mostly smoking (11/12 reports)
- Route of administration was unknown in 14 reports

Health Canada also specifically monitors reports of accidental ingestion of cannabis in the pediatric population. 36% (16/44 reports) involved accidental or unintentional exposure to cannabis, and all these reports involved cannabis from an unknown or illegal source. These reports often originate from the Canadian Surveillance System for Poison Information and the Canadian Pediatric Surveillance Program's study on non-medical cannabis use in children and youth: [Serious and life-threatening events associated with non-medical \(recreational\) cannabis use in Canadian children and youth](#).

⁶ 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, hospital, and/or manufacturer).

Health Canada continues to monitor pediatric exposures suspected to be associated with cannabis and will continue to take appropriate risk mitigation strategies as necessary. In March 2023, Health Canada launched a public education campaign on preventing and identifying cannabis poisonings in children. In May 2023, Health Canada issued an updated public advisory on the accidental ingestion of edible cannabis by children. These can be found at:

- [Cannabis in Canada: Get the facts](#)
- [Public advisory: Accidental ingestion of illegal “copycat” edible cannabis products causing serious harm to children](#)

Case reports involving cannabis products for self-reported medical and non-medical purposes from the legal marketplace and regulated under the *Cannabis Act* and its Regulations form the basis for the remaining portions of this Annual Report.

Adverse reactions associated with legal cannabis products

Figure 2: Reports by reporting month and seriousness

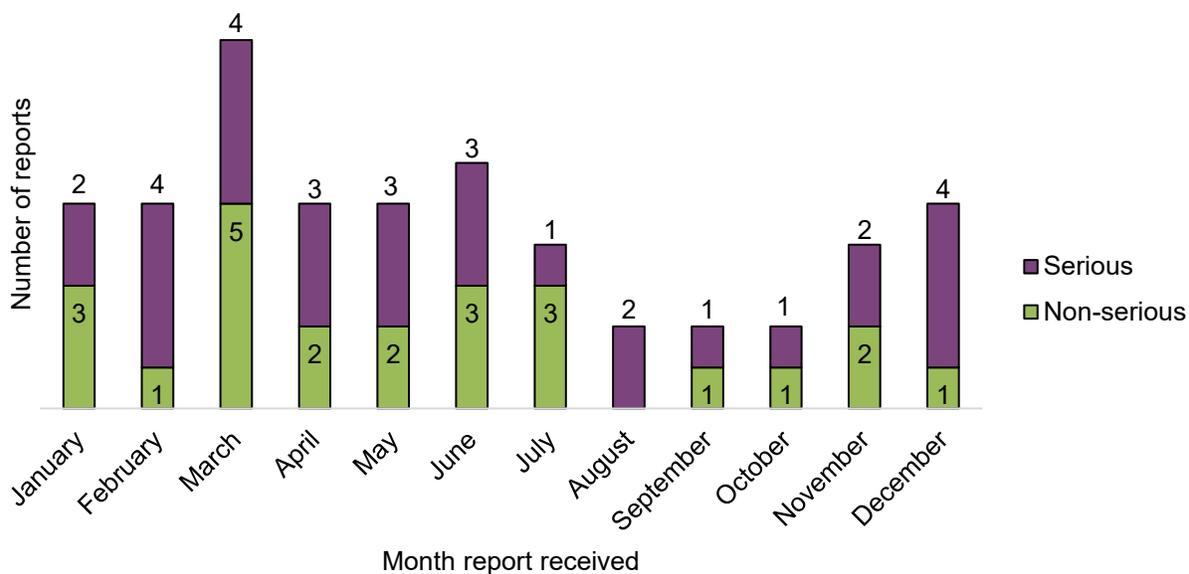


Figure 2 – Text description

Month report received	Number of reports by seriousness		
	Serious	Non-serious	Total
January	2	3	5
February	4	1	5
March	4	5	9
April	3	2	5
May	3	2	5
June	3	3	6
July	1	3	4
August	2	0	2

September	1	1	2
October	1	1	2
November	2	2	4
December	4	1	5
Total	30	24	54

Caveats:

- This figure includes duplicate reports where the case details are the same, but reporters differ (n=2)
- Seriousness is based on the initial report and may be subject to change if additional information is submitted to Health Canada
- This figure excludes 4 cases where seriousness was unknown. In 2023, Health Canada added this new category to capture cases submitted using alternate reporting forms that may not provide the option to identify seriousness. As a result, these cases may be captured differently in other databases
- Reports are presented according to the initial date of receipt by the Canada Vigilance database. The actual date of the adverse reaction may not align with the month that the report was received (lag time between event and reporting)

There were no clear temporal trends observed in the total number of adverse reaction case reports involving legal cannabis products submitted to Health Canada in 2023. The average number of reports received by Health Canada per month during the reporting period was 4.5, ranging from 2 to 9 cases per month.

Some descriptive trends were observed in 2023 compared to 2022. The total number of reports overall (serious and non-serious) and the average number of reports per month decreased in 2023 (total reports: from 95 to 54; average reports per month: from 7.9 to 4.5). In addition, the total number of serious reports submitted to Health Canada decreased (from 72 reports in 2022 to 30 reports in 2023), while the total number of non-serious reports increased slightly (from 23 reports in 2022 to 24 reports in 2023).

Figure 3: Cases by reason for seriousness in serious cases

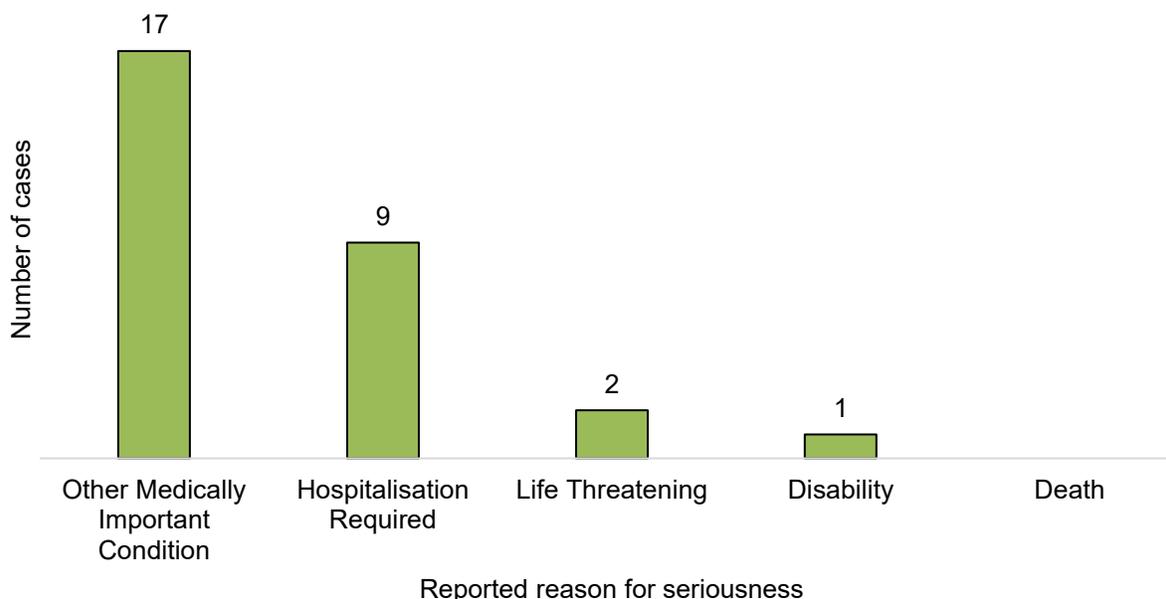


Figure 3 – Text description

Reason for seriousness	Number of cases
Other medically important condition	17
Hospitalisation required	9
Life threatening	2
Disability	1
Death	0
Total	29

Caveats:

- This figure includes unique cases where the reporter indicated that the adverse reaction was serious (n=29)
- This figure excludes 4 cases where seriousness was unknown. In 2023, Health Canada added this new category to capture cases submitted using alternate reporting forms that may not provide the option to identify seriousness. As a result, these cases may be captured differently in other databases
- Each serious case may have more than 1 reason for seriousness as the reporter may select multiple reasons

In 2023, all serious cases submitted to Health Canada involved only one reason for seriousness, for a total of 29 responses for seriousness, spanning four categories, selected by reporters (Figure 3). The most frequently selected category was “other medically important condition” (59%, 17/29 cases), followed by “hospitalization required” (31%, 9/29 cases). The category of “other medically important condition” includes events that are not immediately life threatening or result in death or hospitalization but may jeopardize the patient or may require a medical intervention (for example, ambulatory services, emergency department visits, outpatient visits with an HCP or at-home medical interventions) to prevent a

serious outcome. In 2022, the most common reported reason for seriousness was also “other medically important condition” (59%, 41/69 cases).

There were no cases involving fatal outcomes cases associated with legal cannabis products reported in 2023. Comparatively, 2 fatal outcomes were reported in 2022. Two cases were reported as ‘life threatening’ (a decrease from 4 cases in 2022) and 1 case reported ‘disability’ (an increase from 0 cases in 2022).

Figure 4: Reports by initial reporter type and report source

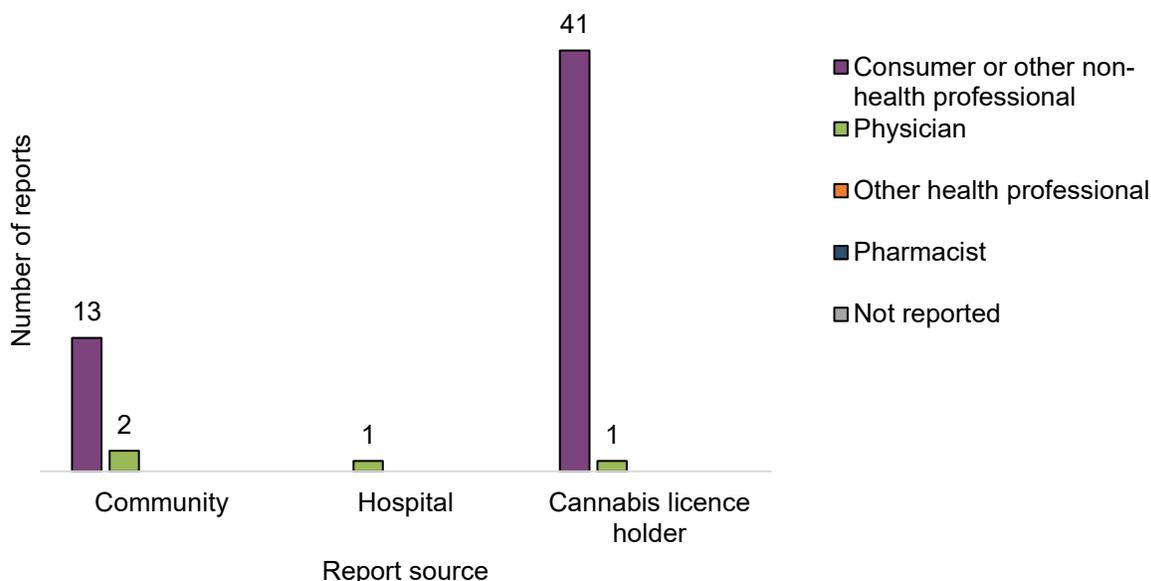


Figure 4 – Text description

Report source	Reporter type					Total
	Consumer or other non-health professional	Physician	Other health professional	Pharmacist	Not reported	
Community	13	2	0	0	0	15
Hospital	0	1	0	0	0	1
Cannabis licence holder	41	1	0	0	0	42
Total	54	4	0	0	0	58

Caveats:

- This figure includes duplicate reports where the case details are the same, but reporters differ (n=2)
- Reports from health care practitioners are considered medically confirmed as per international guidelines,⁷ therefore are distinct from consumer reports

⁷ World Health Organization (2012). Safety monitoring of medicinal products. Reporting system for the general public. Available from: <https://www.who.int/publications/i/item/9789241503198>.

- For purposes of this figure, each report source is further subdivided according to initial reporter type (consumer or health care practitioners, meaning physician, pharmacist or other health professional)
- Report source reflects from whom Health Canada received the report (community, hospital or market authorization holder [for legal cannabis products, this would reflect and is labelled as a licence holder])

Most adverse reaction reports involving legal cannabis products were submitted to Health Canada by cannabis LHs (72%, 42/58 reports). Among cannabis LH reports, the main initial reporter type was primarily a consumer (98%, 41/42 reports). Consumers were also the main initial reporter type from the community (that is, reports submitted directly to Health Canada). Reports from these descriptive reporting trends are consistent with observations from 2022 in that consumers are more inclined to report adverse reactions directly to the LH who then submits a report to Health Canada as per their reporting obligations. In addition, the number of serious and non-serious adverse reaction reports originating from HCPs continued to decline (2018-2019: n=36; 2020: n=18; 2021: n=8; 2022: n=10; 2023: n=4). There was 1 report of an adverse reaction involving legal cannabis submitted by a hospital in 2023, an increase from 0 in 2022.

Under the [Protecting Canadians from Unsafe Drugs Act](#) (that is, Vanessa’s Law), as of December 16, 2019, hospitals are required to submit reports of all serious adverse reactions to Health Canada involving suspect drugs (including drugs containing cannabis) with or without other suspect products. Reports involving a co-suspect drug and co-suspect cannabis are also required to be submitted to Health Canada. However, under the *Cannabis Act* and its Regulations, hospitals may consider submitting, on a voluntary basis, any adverse reactions involving cannabis as the sole suspect product.

Demographics

Figure 5: Cases by age group

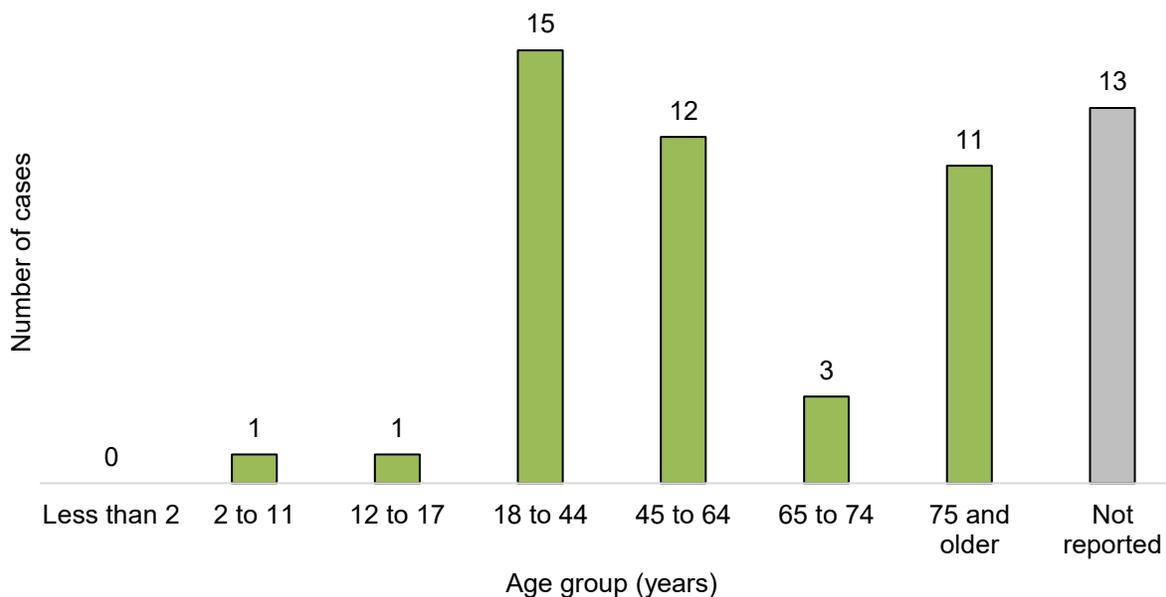


Figure 5 – Text description

Age group (years)	Number of cases
Less than 2	0

2 to 11	1
12 to 17	1
18 to 44	15
45 to 64	12
65 to 74	3
75 and older	11
Not reported	13
Total	56

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)
- In cases where the year of birth and the date of reaction are listed in the report, then the age is calculated (that is, age = date of reaction - year of birth)
- In cases where the year of birth is listed without a date of reaction, the date the report was submitted is used to calculate the age

The average age of individuals in cases involving adverse reactions to legal cannabis products in 2023 was approximately 51.6 years (95% CI: 44.6-58.6) with a range of 8 years to 93 years. This is consistent with 2022 where the average age was 52 years (95% CI: 46-57), ranging from 3 years to 97 years.

When classified using the World Health Organization's Vigilyze database (Vigibase) age groupings, most cases involved persons aged 18-44 years (27%, 15/56 cases). This is consistent with 2022 (18-44 years: 22%, 20/92 cases). Adults aged 65 years and older represented 25% of cases (14/56 cases), as a composite category, an increase from 21% in 2022. Two pediatric cases (<18 years of age) were submitted to Health Canada involving legal cannabis products (1 being authorised for medical purposes) in 2023, similar to 2022 (n=2).

Many cases in 2023 lacked age-related information (23%, 13/56 cases), consistent with 2022 (38%, 35/92 cases).

Figure 6: Cases by sex

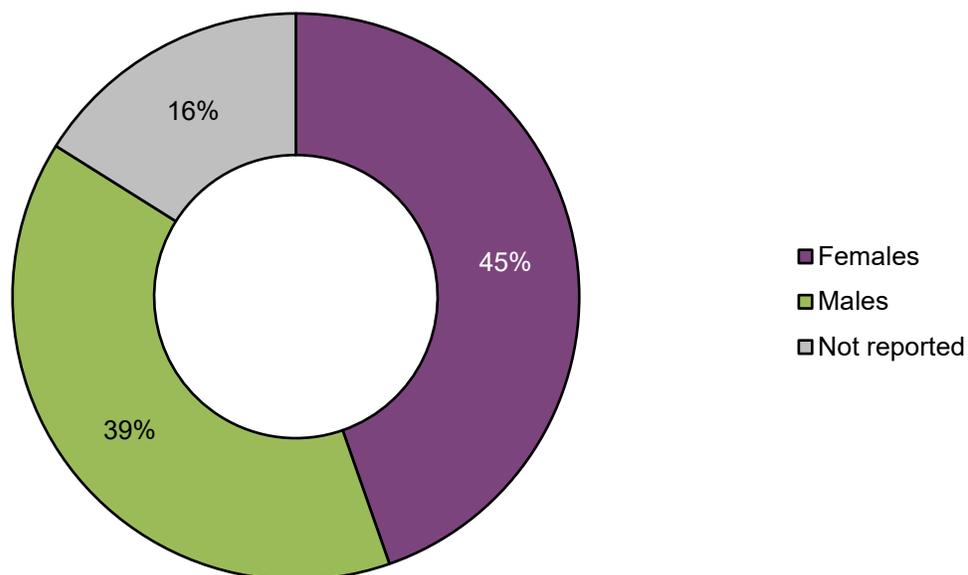


Figure 6 – Text description

Sex	Number of cases	Proportion (%)
Females	25	45
Males	22	39
Not reported	9	16
Total	56	100

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)

Most adverse reaction cases submitted to Health Canada in 2023 involved females (45%, 25/56 cases), while 39% involved males (22/56 cases). The distribution of cases by sex was different than what was observed in 2022 where males made up a greater proportion of the cases compared to females (females: 28%; males: 40%). The proportion of cases not reporting sex has decreased to 16%, compared to 32% in 2022, 28% in 2021 and 8% in 2020.

Sex and age may not be reported for several reasons, including consumers not wanting to disclose this information to licence holders or Health Canada or cases originating from other reporting forms such as the [Cannabis Reporting Form](#), which do not capture this type of demographic information.

Suspected cannabis products

Most adverse reaction cases reported in 2023 were associated with legal cannabis products as the sole suspect product (84%, 47/56 cases). No health products were reported as co-suspects. Health products may include:

- natural health products
- prescription or non-prescription drugs

- other types of health products regulated under the [Food and Drugs Act](#)

However, 39% of cases (22/56 cases) included at least 1 concomitant product. A concomitant product is a product that is used at the time of the adverse reaction but not considered suspect by the reporter as having been responsible for the adverse reaction. These may be:

- health products
- illegal substances
- other regulated substances (for example, alcohol, tobacco or other vaping products such as nicotine or flavors)

A small proportion of cases (11%, 6/56 cases) had 2 or more suspect cannabis products reported, with a range of 2 to 3 cannabis products, similar to 2022 (7%, 6/92 cases). Of note, suspect products are based on the suspicion of the reporter and the involvement of other products, substances or factors cannot always be ruled out. These considerations form part of the clinical evaluation in the clinical summary portion of this report.

Figure 7: Cases by route of administration

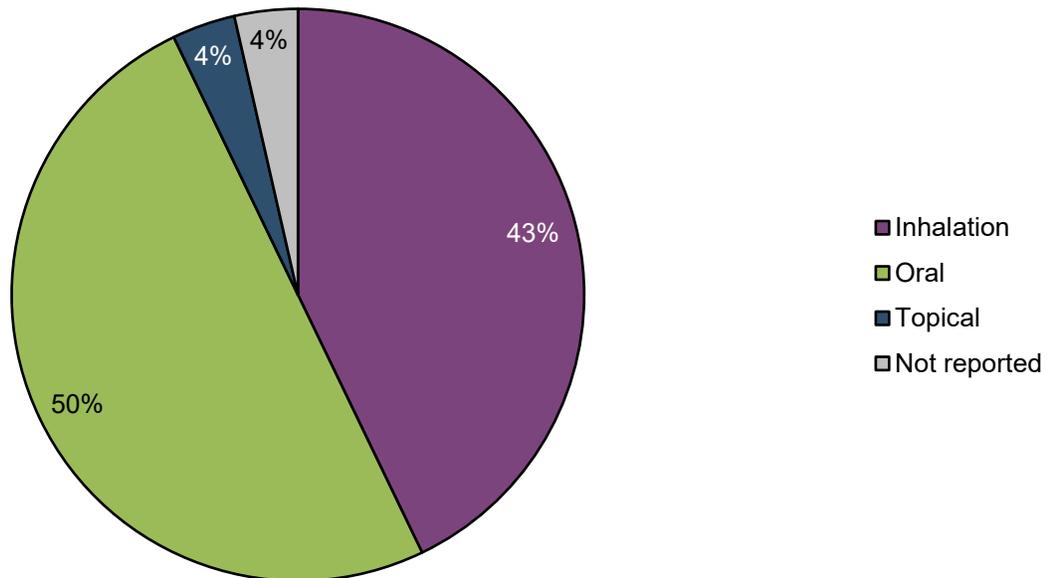


Figure 7 – Text description

Route of administration	Number of cases	Proportion (%)
Inhalation	24	43
Oral	28	50
Topical	2	4
Not reported	2	4
Total	56	100

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)

- This figure describes route of administration of suspect cannabis products in cases, which is coded separately from dosage form (that is, a cannabis oil product may be ingested, applied topically)
- Cases may involve more than 1 suspect cannabis product; therefore, multiple routes of administration may appear for a single case
- Inhalation refers to consuming cannabis through the respiratory tract and may involve smoking or vaporization, among others
- Oral administration refers to consuming cannabis by mouth and may involve ingestion, buccal administration, sublingual administration, etc. meaning that absorption may occur at the level of the gastrointestinal tract as well directly into the bloodstream through oral mucosal tissue

Suspect cannabis products associated with adverse reaction cases almost equally involved cannabis being consumed orally (50%, 28/56 cases) and via inhalation (43%, 24/56 cases). Topical application was involved in 4% of cases (2/56 cases). There were no instances of sublingual administration. Route of administration was unknown in 4% of cases (2/56 cases). These results are similar to 2022 where consumption via inhalation was almost equal to oral administration (47% versus 46% respectively).

Figure 8: Cases by product class and reason for use

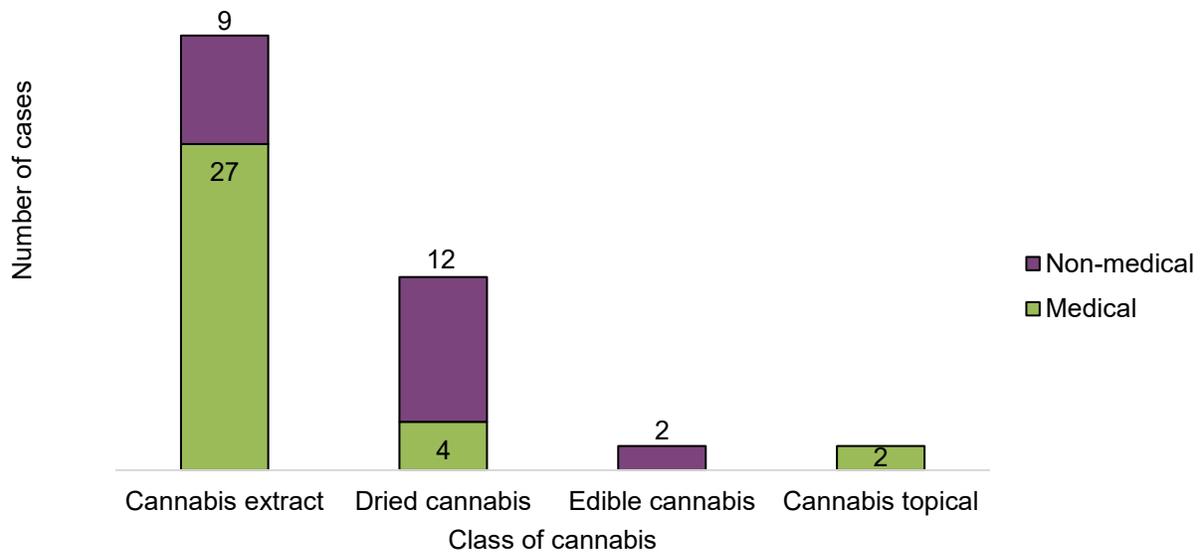


Figure 8 – Text description

Class of cannabis product	Reason for use		
	Medical	Non-medical	Total
Cannabis extract	27	9	36
Dried cannabis	4	12	16
Edible cannabis	0	2	2
Cannabis topical	2	0	2
Total	33	23	56

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)

There was a greater number of adverse reaction cases submitted in 2023 associated with cannabis products used for self-reported medical purposes (59%, 33/56 cases) versus for non-medical purposes (41%, 23/56 cases). A large proportion of the cases involving cannabis products for medical purposes were serious (76%, 25/33 cases). In contrast, most cases involving cannabis products for non-medical purposes were non-serious (83%, 19/23 cases).

Cases were associated with 4 main classes of legal cannabis products (Figure 8):

- cannabis extracts (n=36)
- dried cannabis (n=16)
- edible cannabis (n=2)
- cannabis topicals (n=2)

No cases in 2023 were associated with fresh cannabis. Most cases involving cannabis extract products were used for medical purposes (75%, 27/36 cases), unlike cases involving dried cannabis (25%, 4/16 cases). These descriptive observations are consistent with observations from 2022.

No cases involving transformation of legal cannabis products into homemade edible cannabis were reported 2023.

Figure 9: Cases by suspect cannabis product sub-class and seriousness

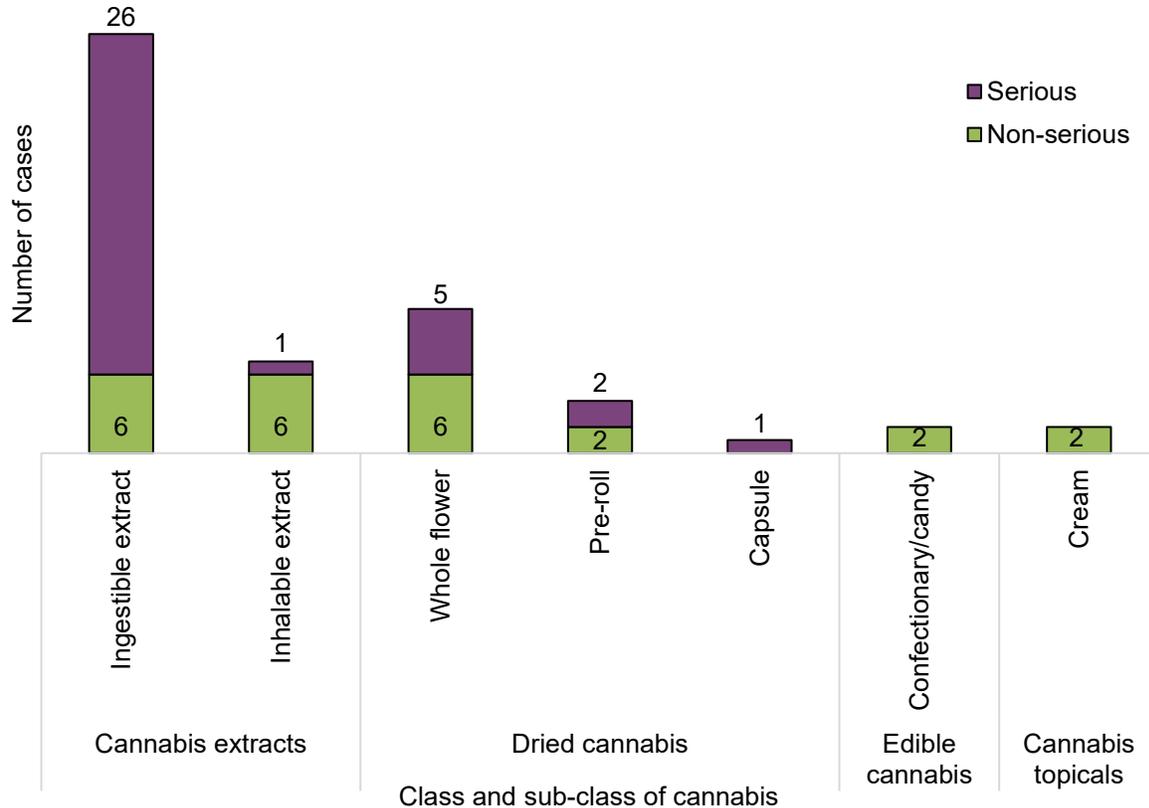


Figure 9 – Text description

Class of cannabis product	Sub-class of cannabis product	Total number of products by seriousness		
		Serious	Non-serious	Total
Cannabis extract	Ingestible extract	26	6	32
	Inhalable extract	1	6	7
Dried cannabis	Whole flower	5	6	11
	Pre-roll	2	2	4
	Capsule	1	0	1
Edible cannabis	Confectionary/candy	0	2	2
Cannabis topical	Cream	0	2	2
Total		35	24	59

Caveats:

- This figure was developed by Health Canada through manual categorization of cases according to their sub-class of suspect cannabis products
- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)
- This figure excludes 4 cases where seriousness was unknown. In 2023, Health Canada added this new category to capture cases submitted using alternate reporting forms that may not provide the option to identify seriousness. As a result, these cases may be captured differently in other databases.
- Cases may have multiple suspected cannabis product reported across different sub-classes of cannabis. For this reason, the total number reflected in the table according to count of suspect products by sub-classes and seriousness may exceed the number of unique cases
- Cannabis extracts as a class involves a diverse group of product forms including oral liquids or drops, softgels, capsules or tablets, sublingual sprays, dissolvable strips or highly concentrated extracts like shatter, wax, rosin, resin or vaping liquids
- Dried cannabis includes whole dried flower, milled flower, and pre-rolls
- Edibles includes food-like formats (chocolate, confectionary, mints) and beverages
- Oral sprays (ingestible) are noted separately from ingestible liquid extracts based on their intended sublingual or oro-mucosal use (that is, inside the mouth) that may absorb directly into the bloodstream

Cannabis extracts were among the most frequently reported class of cannabis products involved in adverse reaction cases, along with dried cannabis. Within the category of cannabis extracts, ingestible oils in liquid formats (bottled oils with dropper, softgels) and inhalable extracts (vaping liquids, resin) were most frequently involved subclasses. This is generally consistent with observations from 2022, where ingestible oils in liquid form were also the most frequently involved product subclass.

When disaggregated by sub-class, young to middle aged adult groups (18 to 64 years) were more frequently involved in adverse reaction cases with inhalable extracts (for example, vaping liquids), dried flower, cannabis topicals and cannabis edibles, while older adults (65 years and older) were more frequently involved in adverse reaction cases with ingestible oils in liquid formats. This is generally consistent with data from 2022 where young-to-middle aged adult groups (18 to 64 years) were more frequently involved in adverse reaction cases with vaping liquids and oral sprays, while older adults (65

years and older) were more frequently involved in adverse reaction cases with ingestible oils in liquid form, including softgel capsules.

Types of individual events reported

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

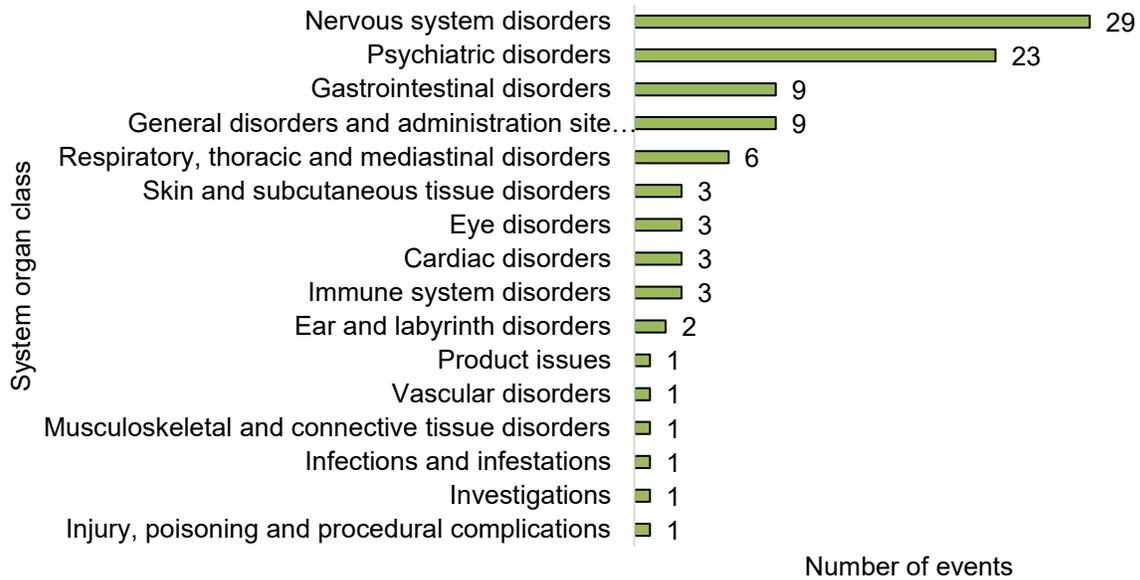


Figure 10 – Text description

System organ class	Number of events
Nervous system disorders	29
Psychiatric disorders	23
Gastrointestinal disorders	9
General disorders and administration site conditions	9
Respiratory, thoracic and mediastinal disorders	6
Skin and subcutaneous tissue disorders	3
Eye disorders	3
Cardiac disorders	3
Immune system disorders	3
Ear and labyrinth disorders	2
Product issues	1
Vascular disorders	1
Musculoskeletal and connective tissue disorders	1
Infections and infestations	1
Investigations	1
Injury, poisoning and procedural complications	1

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)

- This 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 through a causality assessment
- Each case may describe 1 or more individual medical events reflective of signs, symptoms, diseases, diagnoses, investigations, and procedures
- Events are coded according to MedDRA, which provides standardized medical terminology in hierarchical groupings. The highest-level grouping is the SOC
- 1 adverse reaction case may be represented across multiple SOCs, and is influenced by how individual events (signs, symptoms, observations or diagnostics) are reported

In 2023, Health Canada assessed a total of 207 adverse events for causality. Of these, 96 individual adverse events were assessed as being certainly, probably or possibly related to the suspected cannabis product for cases. Other events were examined but were unassessable or deemed unlikely to be related to the cannabis.

When grouped at the broadest grouping level (that is, SOC) the 5 most frequent categories were:

- nervous system disorders (30%, 29/96 events);
- psychiatric disorders (24%, 23/96 events);
- general disorders and administration site conditions (9%, 9/96 events);
- gastrointestinal disorders (9%, 9/96 events); and
- respiratory, thoracic and mediastinal disorders (6%, 6/96 events).

The top 5 SOCs for 2023 are consistent with the top 5 SOCs reported in 2022, but in varying order.

Figure 11: Frequency of individual events

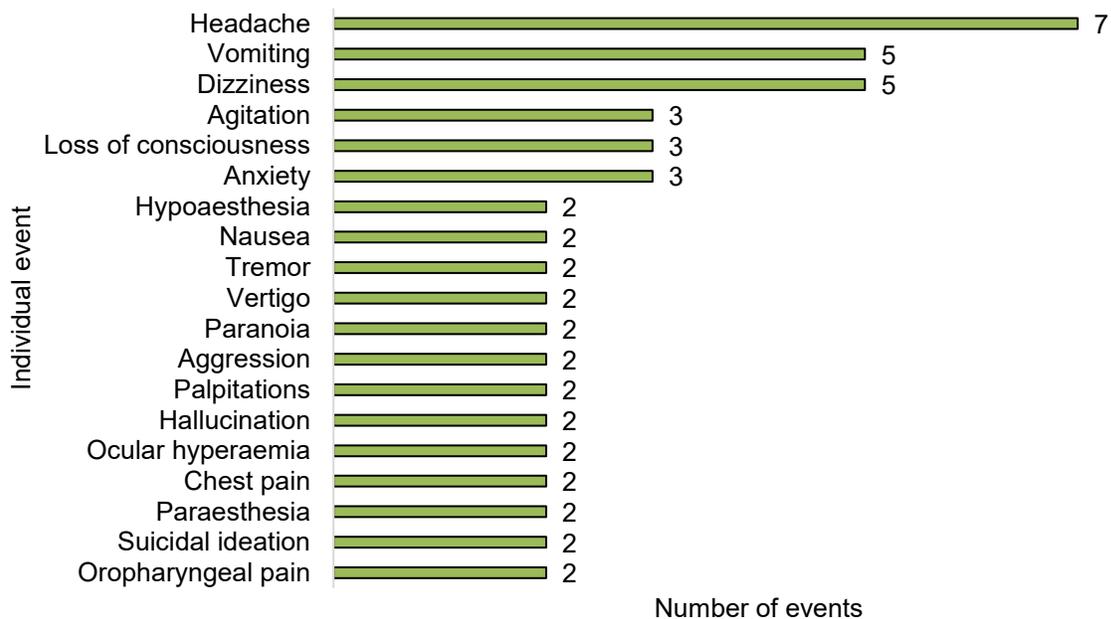


Figure 11 – Text description

Individual events	Number of events
Headache	7
Vomiting	5
Dizziness	5
Agitation	3
Loss of consciousness	3
Anxiety	3
Hypoaesthesia	2
Nausea	2
Tremor	2
Vertigo	2
Paranoia	2
Aggression	2
Palpitations	2
Hallucination	2
Ocular hyperaemia	2
Chest pain	2
Paraesthesia	2
Suicidal ideation	2
Oropharyngeal pain	2

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)
- 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). Other individual events reported less frequently do not appear in this figure
- Individual events are coded using MedDRA terminology based on what was described in the case report verbatim
- Each case can have multiple individual events reported therefore the number of individual events exceeds the total number of unique cases
- Several types of hallucination were combined to create an all-inclusive hallucination category. This category includes auditory hallucination, visual hallucination, mixed hallucination, hypnagogic hallucination and pseudo-hallucination

As noted in Figure 11, the most frequently reported individual events assessed by Health Canada as being certainly, probably or possibly related to the suspected cannabis product for cases received in 2023 were:

- headache (7%, 7/96 events)
- vomiting (5%, 5/96 events)

- dizziness (5%, 5/96 events)
- agitation (3%, 3/96 events)
- loss of consciousness (3%, 3/96 events)
- anxiety (3%, 3/96 events)

Headache was also the top individual event reported in 2022. However, the remaining 4 events from 2022 differ from those reported in 2023. They included seizure, hallucination, dyspnoea and drug ineffective.

Figure 12: Frequency of individual events by cannabinoid ratio

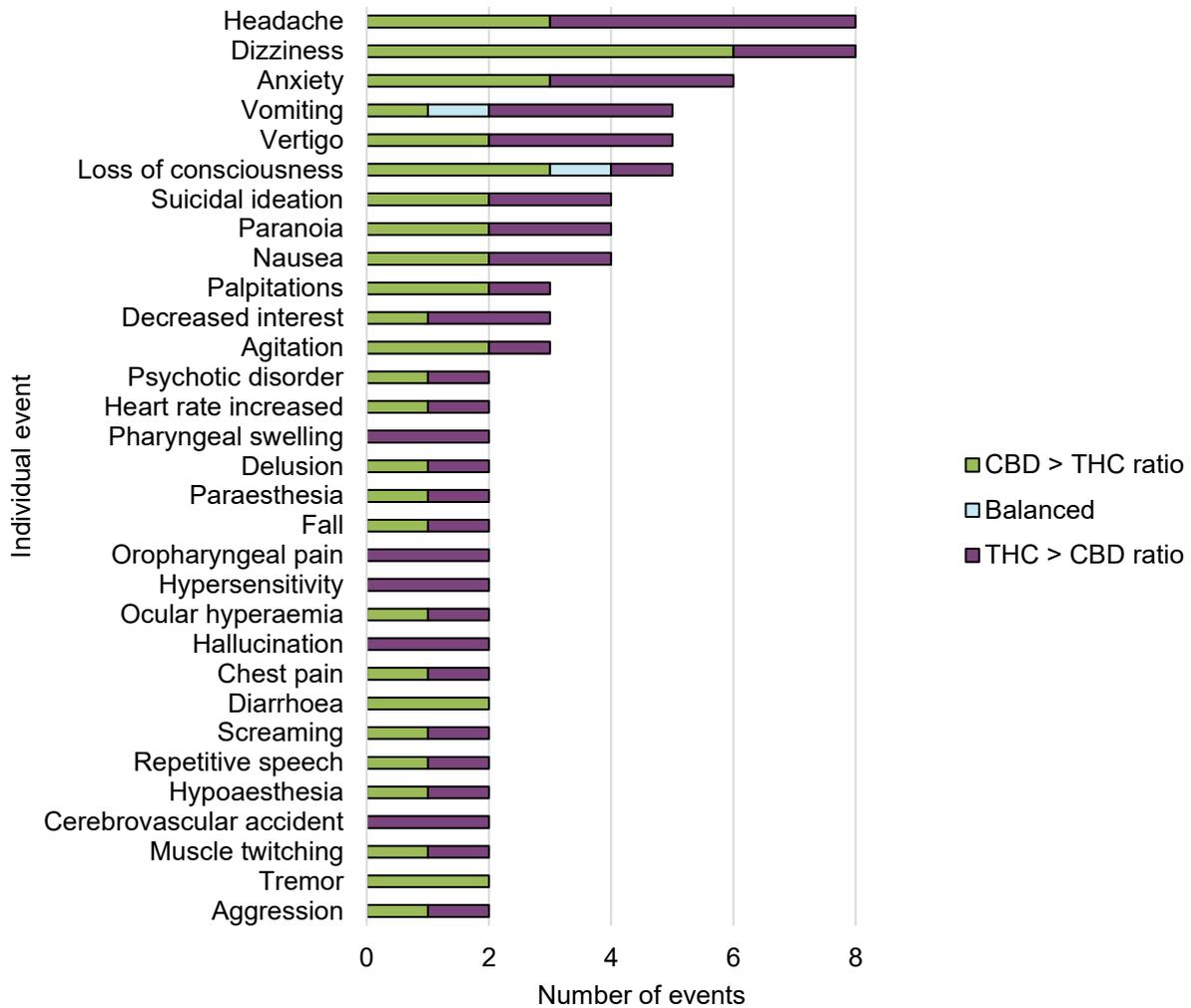


Figure 12 – Text description

Individual events	Cannabinoid dominance			
	CBD > THC ratio	Balanced	THC > CBD ratio	Total
Headache	3	0	5	8

Dizziness	6	0	2	8
Anxiety	3	0	3	6
Vomiting	1	1	3	5
Vertigo	2	0	3	5
Loss of consciousness	3	1	1	5
Suicidal ideation	2	0	2	4
Paranoia	2	0	2	4
Nausea	2	0	2	4
Palpitations	2	0	1	3
Decreased interest	1	0	2	3
Agitation	2	0	1	3
Psychotic disorder	1	0	1	2
Heart rate increased	1	0	1	2
Pharyngeal swelling	0	0	2	2
Delusion	1	0	1	2
Paraesthesia	1	0	1	2
Fall	1	0	1	2
Hypersensitivity	0	0	2	2
Oropharyngeal pain	0	0	2	2
Ocular hyperaemia	1	0	1	2
Hallucination	0	0	2	2
Chest pain	1	0	1	2
Diarrhoea	2	0	0	2
Screaming	1	0	1	2
Repetitive speech	1	0	1	2
Hypoaesthesia	1	0	1	2
Cerebrovascular accident	0	0	2	2
Muscle twitching	1	0	1	2
Tremor	2	0	0	2
Aggression	1	0	1	2

Caveats:

- This figure excludes duplicate reports where the case details are the same, but reporters differ (n=2)
- 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 sufficient information for assignment of cannabinoid ratio (that is, unclassified), therefore, the events in this figure may differ from those observed in Figure 11. Other events were reported during the reporting period but do not appear in this figure due to limitations of space in the table
- This figure was manually created by Health Canada by classifying each suspect cannabis product to a cannabinoid ratio based on available product details and assigning all individual events within

a case to all 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 “balance” is considered a THC:CBD ratio between 1.2:1 and 1:1.2

Overall, adverse reaction cases from 2023 more frequently involved products with a greater THC to CBD ratio (that is, a THC:CBD ratio greater than 1.2:1) compared to products containing a greater CBD to THC ratio (that is, a CBD:THC ratio greater than 1.2:1). As highlighted in Figure 12, certain individual medical events were more frequently reported with products containing a greater ratio of THC to CBD, whereas others were more frequently reported with products containing a greater ratio of CBD to THC.

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

- headache
- vomiting
- hallucination
- hypersensitivity
- pharyngeal swelling
- oropharyngeal pain
- cerebrovascular accident

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

- dizziness
- loss of consciousness
- diarrhoeatremor

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

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

However, the ability to draw strong conclusions is limited due to the complex nature of the available data.

SEX AND GENDER BASED ANALYSIS PLUS OF 2023 ADVERSE REACTION DATA

Figure 13 – SGBA plus: Cases by sex

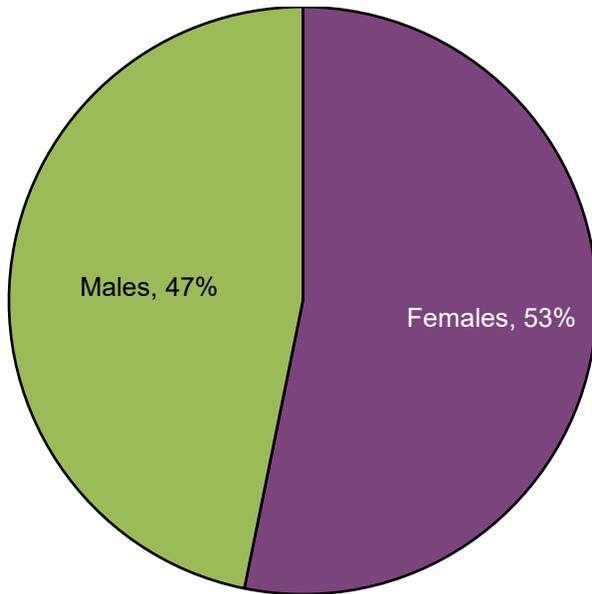


Figure 13 – Text description

Sex	Number of cases	Proportion (%) of total
Females	25	53
Males	22	47
Total	47	100

A total of 47 adverse reaction cases included a designation for sex in 2023. 53% (25/47 cases) involved females. Females were involved in 65% (17/26 cases) of all serious cases with a reported sex, and 62% of cases (18/29 cases) reporting use of cannabis for medical purposes. Non-serious cases and use 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. Where age was reported (42/47 cases), the average age of females was 55.1 years (95% CI: 45.0-65.2) and 47.1 years for males (95% CI: 35.8-58.3).

Under 65 years:

Females, n=14; males, n=13

65 years or older:

Females, n=9; males, n=5

Figure 14 – SGBA plus: Cases by age group (years)

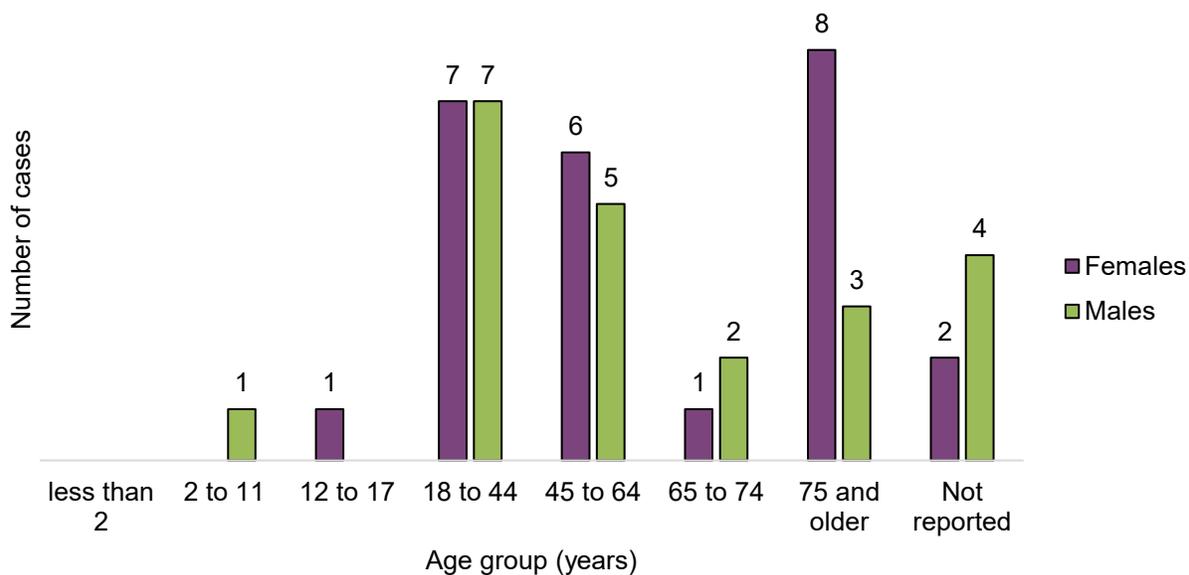


Figure 14 – Text description

Age group (years)	Number of cases	
	Females	Males
Less than 2	0	0
2 to 11	0	1
12 to 17	1	0
18 to 44	7	7
45 to 64	6	5
65 to 74	1	2
75 and older	8	3
Not reported	2	4
Total	25	22

Adverse reactions cases involving cannabis extracts (oils and softgels) and topical cannabis more frequently involved females than males. Conversely, dried cannabis and edibles more frequently involved males than females.

Table 1: Top individual events reported by sex	
Females	Males
Anxiety (n=4)	Headache (n=6)
Headache (n=4)	Oropharyngeal pain (n=3)
Dizziness (n=4)	Vomiting (n=3)

CLINICAL EVALUATION OF SERIOUS AND MEDICALLY IMPORTANT CASES

Summary of serious and medically important adverse reactions

All individual events within a serious adverse reaction case that is reported to Health Canada are assessed for causality. The causality of individual events is based on the information reported in the cases and through follow-up where possible. Cases may lack sufficient information to assess the causal association between event(s) 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 product(s) and the adverse event(s). This practice supports the identification of potential risk concerns that may require further investigation or actions by the regulatory authority (e.g. Health Canada) and/or the licence holder.

Table 2: Causality assessment of serious cases	
<i>Causality Assigned</i>	<i>Number of events</i>
Certain	0
Probable	16
Possible	87
Unlikely	26
Unassessable	25
Total	154

Overall, most events were assigned a causality of 'Possible' (56%, 87/154 events), meaning there was a reasonable possibility that the cannabis product may have contributed to the adverse reaction, but the contribution of other factors could not be ruled out (for example, concomitant medications, co-morbidities, etc.).

No events were assigned a causality of 'Certain', for which a stringent level of evidence is required, including both laboratory and medical confirmation. As well, the case must lack any other alternative explanations.

There were 16/154 events assigned a causality of 'Probable' (10%), 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 16 events assigned a causality of 'Probable' represents 4 cases:

- 3 were associated with legal cannabis extract products for ingestion (softgel capsules, n=2; oils, n=1)
- 1 case involved dried cannabis

All of these cases reported cannabis as the sole suspect product. No other health products were reported as co-suspects; 1 case reported use of concomitant health products. In addition, 3 out of 4 cases had reported pre-existing medical conditions, and 3 out of 4 cases were using cannabis products for self-reported medical purposes (indications of use included migraine and sleep disorder).

There were 25/154 events determined to be 'Unassessable' (16%), meaning there was insufficient information to establish a causal association between the cannabis product and the reported adverse reaction.

There were 26/154 events assigned a causality of 'Unlikely' (17%), meaning that 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 by Health Canada. An identified risk means that the association between a drug (for example, cannabis) and event has been proven, and that this risk could have implications for public health.⁸

Most serious or medically important cases with 'Probable' causality were considered to involve known identified risks (that is, the risk has already been identified and characterized in Health Canada's [Information for Health Care Professionals document](#); last updated: Spring 2018). These include:

- Neurological reactions (for example, headache, light-headedness)
- Psychiatric reactions (for example, panic, anxiety, hallucinations)
- Respiratory non-infectious reactions (for example, throat irritation)
- Cardiovascular reactions (for example, atrial fibrillation, palpitations, tachycardia)
- Hypersensitivity /allergic reactions (for example, systemic hypersensitivity reactions)

Important potential risks during the reporting period

An important potential risk of a cannabis-drug interaction resulting in serotonin syndrome was observed in adverse reaction data with cannabis products during this reporting period.

A potential risk means that there is suspicion of association between a drug (for example, cannabis) and the event, which is yet to be proven, and that this risk could have implications for public health.⁸

Additionally, a risk of arrhythmia with the use of cannabis products was identified at the end of 2022; and Health Canada has completed a preliminary signal assessment in 2023; and is currently conducting a signal assessment on this issue and will recommend appropriate measures as necessary.

Risk of cannabis-drug interaction between cannabis (THC, CBD, Balanced) and venlafaxine resulting in serotonin syndrome

This important potential risk of a drug interaction was identified in 2023 and a preliminary signal assessment was completed. This drug interaction resulting in mild serotonin syndrome has not been previously identified in the literature and is a new safety signal. Only one domestic case has been identified in which the cannabis – venlafaxine hydrochloride interaction resulted in a presumptive case of serotonin syndrome. No reports regarding a similar interaction were identified on WHO Vigilyze. In this particular case, this cannabis - drug interaction resulting in serotonin syndrome was determined to be

⁸ European Medicines Agency. (2017). Guideline on good pharmacovigilance practices (GVP): Annex I - Definitions (Rev 4). https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-4_en.pdf

probable. The preliminary signal assessment identified three hypothetical pharmacological pathways in which the cannabis product containing THC and CBD could result in serotonin syndrome when co-administered with venlafaxine hydrochloride. The first proposed pathway is that cannabidiol is a potential inhibitor of the CYP2D6 enzyme and venlafaxine hydrochloride is metabolized mainly by CYP2D6, therefore, concomitant use of venlafaxine and cannabis can theoretically increase venlafaxine hydrochloride plasma concentration that may result in serotonin syndrome. The second proposed pathway is that THC may inhibit monoamine oxidase (MAO), as demonstrated *in vivo*. The potential inhibition of MAO can result in an increase in serotonin and could result in serotonin syndrome. Lastly, CBD could inhibit P-glycoprotein (P-gp) efflux pumps, which could decrease the efflux of venlafaxine hydrochloride and consequently increase its concentration and the amount of serotonin in the body. Health Canada will continue to monitor the potential risk of serotonin syndrome due to drug interactions with cannabis products from adverse reaction reports, international regulatory agencies, and scientific literature including published case reports. As more information becomes available, Health Canada will reassess this signal and take appropriate measures as necessary.

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

This important potential risk was identified at the end of 2022 and Health Canada has completed a preliminary signal assessment. A search of the Canada Vigilance Database has identified 35 cases of cardiac arrhythmias associated with cannabis use; of which 25 cases were reported as serious. Causality was assessed, using WHO-Uppsala Monitoring Centre criteria, for these 25 cases; in which 2 were assessed as 'unlikely', 19 were assessed as 'possible', and 4 were assessed as 'probable'. A search of the WHO Vigilyze database identified 145 foreign cases of cardiac arrhythmias associated with cannabis consumption. The risk of arrhythmia with cannabis use has been referenced in Health Canada's "Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids" as a potential adverse effect of cannabis use. Health Canada is currently following up this preliminary signal assessment with an in-depth signal evaluation.

Ongoing monitoring of safety signals

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

- Risk of blood clotting in individuals that concurrently use cannabis products and estrogen containing combined oral contraceptives;
- Risk of aspergillosis amongst immuno-competent consumers using dried cannabis;
- Risk of hallucinations amongst consumers using cannabidiol-containing products;
- Risk of hypoglycemia events amongst cannabis users; and
- Risk of cannabis-drug interactions (warfarin, topiramate, clobazam, metronidazole, lorazepam, anti-depressants etc.)

Fatal cases during the reporting period

There were no fatal cases received during this reporting period.

NOTE TO READERS

Adverse reaction case reports with cannabis submitted to Health Canada are received and entered into the Canada Vigilance database. The Marketed Health Product Directorate (MHPD) of the Health Products and Food Branch (HPFB) collects, monitors and analyses adverse reactions submitted to the Canada Vigilance database, amongst other activities, and codes and houses adverse reaction reports for cannabis. The Controlled Substances and Cannabis Branch (CSCB) is responsible for the monitoring,

detection, prioritization, evaluation and aggregate reporting of adverse reactions associated with cannabis (pharmacovigilance).

Voluntary reports from the public may be received via the online reporting form, through the toll-free number or through the printable form via electronic fax or mailing to Health Canada. Mandatory reports are submitted by licence holders to meet their regulatory reporting obligations for serious adverse reactions under the *Cannabis Regulations* and are submitted through fax or mail, unless the company is registered to submit electronic reports directly to the Canada Vigilance database (specific format must be met). Cannabis complaints and product quality issues may also be referred via the [Cannabis Reporting Form](#) from Health Canada. Incidents involving cannabis accessories (for example, mechanical, physical or electrical issues or failure of a cannabis accessory and associated injuries) can be reported via the [Consumer Product Incident Reporting Form](#) from the Healthy Environment and Consumer Safety Branch. All cannabis 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 developed, maintained and updated by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use as an international set of standardized medical terms for symptoms, signs, diseases, syndromes and diagnoses.
2. Case reports involving cannabis as a substance in a suspected role are coded as 'cannabis sativa' at the active ingredient level, irrespective of the identity of the cannabis product (legal, illegal, unspecified, undetermined).
3. Case reports involving a legal cannabis product in a suspected role (identified either by product name or licence holder) are classified according to the intended use: cannabis product used for medical purposes (medical cannabis) or used for non-medical purposes (non-medical cannabis), based on the information in the report. Cannabis use for medical purposes includes reports described having a medical authorization document; or, a reported medical or therapeutic purpose or indication, without mention of a medical authorization document. If there is no reported reason for use provided in the report, minimal details or intended use for non-medical purposes, the report is classified as non-medical cannabis.
4. Case reports are coded as serious as reported if at least 1 criterion for seriousness is selected:
 - death
 - life-threatening
 - admitted to the hospital
 - lengthened hospital stay
 - disability
 - birth defect
 - other medically important condition may also be selected by the reporter
5. According to international pharmacovigilance guidelines (ICH guidelines⁹), medically important conditions may also be considered serious under certain circumstances and therefore are an option to select when reporting an adverse reaction to Health Canada, and any adverse reaction case identified as such are further reviewed. However, these cases technically fall outside of the regulatory definition of a serious adverse reaction under the *Cannabis Regulations*.

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

⁹ European Medicines Agency (2004). ICH Topic E2D: Post Approval Safety Data Management Step 5. https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-12.pdf

- Screening of all new cannabis case reports to ensure they are:
- Coded appropriately according to the MedDRA
 - classified as either cannabis for medical or non-medical purposes (legal classes)
 - product names are accurate
- Case reports involving a suspected non-compliance (for example, the presence of visual mould, metallic taste, unusual odour) are referred to the Compliance Directorate for verification.
- Non-serious reports are screened by Health Canada and those deemed to be medically important events are included for further assessment (causality assessment).
- All serious and medically important case reports undergo further investigation and assessment, including:
 - conducting follow-up for additional information on product details or clinical details of cases to aid in assessment
- Conducting a cursory (that is, initial) causality assessment for each event reported in the case report. Causality assessment is based primarily on the [WHO-UMC system for standardised case causality assessment](#)
 - undergoing a comprehensive individual causality assessment for all fatal and life-threatening cases, which, are considered priority reports
- Any cases involving new or unexpected adverse reactions of interest undergo preliminary assessment (signal prioritization) to determine if they should be further evaluated
- A case series evaluation (signal assessment) is conducted in the event of a cluster or related cases involving new adverse reactions of interest. These comprehensive assessments involve the determination of biological plausibility based on published literature, domestic as well as international adverse reaction data (WHO Vigibase) and recommend appropriate risk mitigation strategy as necessary.

REPORTING AN ADVERSE REACTION INVOLVING A CANNABIS PRODUCT

Licence holders must submit serious adverse reaction reports, as defined by the *Cannabis Regulations*, involving a cannabis product. They are encouraged to voluntarily submit non-serious adverse reaction reports involving a cannabis product. More information can be found in the [Cannabis adverse reaction reporting guide for licence holders](#).

Consumers and health care practitioners 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 cannabis product.

[Report an adverse reaction to Health Canada](#)



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_oss-cannabis_bss@hc-sc.gc.ca.