COMPLIANCE PROMOTION: COMPLAINT INVESTIGATIONS, ADVERSE REACTION REPORTING, AND RECORD KEEPING UNDER THE CANNABIS REGULATIONS

Dear cannabis licence holder,

At Health Canada, we are committed to supporting cannabis licence holders (LHs) in achieving high standards of regulatory compliance. Following recent inspections of LHs, Health Canada would like to bring to your attention certain requirements under the *Cannabis Regulations* (CR) related to adverse reactions, particularly in the areas of complaint investigations and adverse reaction reporting.

CLARIFICATION ON COMPLIANCE REQUIREMENTS

1. COMPREHENSIVE INVESTIGATIONS UNDER THE QUALITY ASSURANCE PERSON'S OVERSIGHT

Holders of a licence for processing are required to retain the services of a Quality Assurance Person (QAP) that is responsible for investigating every complaint received in respect of the quality of the cannabis, including adverse reactions, and, if necessary, immediately taking measures to mitigate any risk. On March 12, 2025, the *Regulations amending certain regulations concerning cannabis (streamlining of requirements)* came into force permitting these activities to be assigned to other qualified individuals, provided the QAP maintains overall responsibility and accountability for these activities. See paragraphs 19(2)(b)&(c) and 88(1)(a)&(b) and 88(2) of the CR for more information on the responsibilities of a processor's QAP regarding quality complaints.

A complete and well-documented investigation is a key factor in addressing potential issues and maintaining proper records. In turn, these records, including all necessary details such as the type of adverse reaction (if applicable), product information and any corrective actions taken, demonstrate accountability and identify which complaints may fall under adverse reaction reporting provisions.

All quality complaints involving an adverse reaction must be included in your annual summary report of all adverse reactions (see sections 3-5 below for more information on adverse reaction reports).

2. EFFECTIVE INFORMATION GATHERING

Standard operating procedures (SOPs) that are in accordance with good production practices must be in place and followed. See section 80 of the CR and the Good production practices guide for cannabis for more information on SOP expectations.

While having established procedures is essential, it's equally important to ensure consistent adherence to them, particularly when investigating complaints and possible adverse reactions. As mentioned above, the QAP or the assigned qualified individual, must investigate each complaint received in respect to the quality of cannabis. Additionally, qualified personnel should review instances of adverse reactions. Improving internal procedures regarding complaint follow-up can enhance the effectiveness of responses and corrective actions.

An essential step in investigating complaints is distinguishing between those related to product quality and those involving adverse reactions, which can be determined through a methodical information-gathering process. LHs are encouraged to focus on refining their information collection practices when responding to product-related reports. By gathering comprehensive details from reporters, you can more accurately assess and categorize complaints and identify cases of adverse reactions, and determine the appropriate regulatory response, ensuring both compliance and product safety.

If a complaint includes an adverse reaction, as defined under section 248 of the CR, it is important to determine the classification of the adverse reaction as part of the concise and critical analysis in your annual summary report for adverse reactions.

3. UNDERSTANDING ADVERSE REACTION CLASSIFICATIONS

It is essential that all adverse reactions be identified, recorded and investigated. For LHs to accurately distinguish between **adverse reactions**, **serious adverse reactions,** and **medically important events**, please consider the table below for definitions and non-exhaustive examples, as a guide:

	Definition	Example
Adverse Reaction	A noxious and unintended response to cannabis or a cannabis accessory that contains cannabis. This includes any unintended or unwanted effect, regardless of whether the reaction was expected based on the product's use.	A report of cough or headache, as it represents an unwanted response.*

	Definition	Example
Serious Adverse Reaction	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	A report which indicates that an individual was hospitalised or a report which indicates that an individual died while using cannabis.
Medically Important Event	An adverse reaction that may not be immediately life-threatening or result in death or hospitalization but still poses a significant risk to the patient or consumer. This type of reaction may require medical attention or intervention to prevent more severe outcomes, such as those that would qualify as serious adverse reactions.	A report of an anaphylactic reaction that requires the attention of a health professional or administration of epinephrine, where the consumer is not admitted to the hospital.

Reminders:

A non-serious adverse reaction is one that does not meet any of the criteria for a serious adverse reaction under the *Cannabis Regulations*, and is not determined to be a medically important event. LHs may **voluntarily report** non-serious adverse reactions, especially if new or unexpected patterns emerge (e.g., changes in severity, frequency, or trends).

However, LHs **must** report all serious adverse reactions to Health Canada within 15 calendar days of becoming aware of them.

Health Canada asks that medically important events – those that may not be immediately life-threatening but could jeopardize a patient or require intervention to prevent serious outcomes –also be reported on an expedited basis (within 15 calendar days).

Additionally, **all adverse reactions**, including non-serious ones, must be documented and critically analyzed for inclusion in your annual summary report.

**Note that a report of "not high enough" (without any reported noxious responses) does not meet the criteria for an adverse reaction, as there is no noxious response to the consumer. These reports would not be included in the annual summary report unless they also include an adverse reaction (i.e. a noxious response).*

We encourage LHs to review their internal processes and ensure that all employees involved in complaint investigations and adverse reaction reporting are familiar with these definitions and good pharmacovigilance practices. This information is outlined in the Cannabis adverse reaction reporting guide for licence holders which contains more detailed examples and guidance on adverse reaction reporting.

4. REPORTING SERIOUS ADVERSE REACTIONS

Serious adverse reactions must be reported within 15 calendar days of becoming aware of them as per paragraph 248.1(1)(a) of the CR. Serious adverse reactions are also to be included in the annual summary report.

In situations where multiple LHs are involved in the production, sale, or distribution of cannabis products, it is important to clearly understand and follow the reporting obligations. Ensuring that all parties involved are aware of their responsibilities can help to streamline reporting and prevent gaps in compliance. For more information on the responsibilities in regard to adverse reaction reporting by the various parties involved in the production, sale, or distribution of cannabis products, refer to Requirements for adverse reaction reporting and Reporting procedures in the Cannabis adverse reaction reporting guide for licence holders.

5. IMPROVING THE QUALITY OF ANNUAL SUMMARY REPORTS

LHs must maintain records of all adverse reactions in an annual summary report as per paragraph 248.1(1)(b) of the CR. This report goes beyond a simple summary; it must contain a concise and critical analysis of all adverse reactions from the previous 12 months. For details on the requirements, contents and format of the annual summary report, visit Cannabis adverse reaction reporting: Annual summary report.

Additional support on this topic is available, please refer to the section below entitled “New guidance & learning opportunities” for more information.

KEY TAKEAWAYS

- ✓ Investigate product quality complaints, including identifying which fall into the category of adverse reactions.
- ✓ Strengthen your procedures for distinguishing adverse reactions from complaints related to quality by gathering comprehensive information from reporters.
- ✓ Serious adverse reactions must be reported to Health Canada within 15 calendar days after becoming aware of the adverse reaction.
- ✓ Health Canada asks that medically important events be reported on an expedited basis as well (within 15 calendar days of initial receipt of the information).
- ✓ Ensure that you actively prepare and maintain annual summary reports that include a concise and critical analysis of all adverse reactions from the previous 12 months.

NEW GUIDANCE & LEARNING OPPORTUNITIES

In our ongoing efforts to support compliance, Health Canada offers the following:

1. New guidance on Cannabis adverse reaction reporting: Annual summary report to assist LHs in preparing annual summary reports.
2. Updated guidance on cannabis adverse reaction reporting for licence holders to provide more clarity to LHs regarding expectations and obligations of adverse reaction reporting.
3. Virtual learning series webinars
    - A session on adverse reaction reporting and complaint handling was delivered on November 27, 2024. To access the recording, please view webinar #6: Adverse Reaction (AR) and Cannabis Tracking System (CTS) Reporting.

The educational materials above provide an excellent opportunity to gain further clarity on regulatory requirements and best practices. Make sure to stay informed via updates continually communicated onto the Cannabis and Industrial Hemp webpage and follow us on Eventbrite for notifications of new events.

RESOURCES

See below for a list of helpful resources available online:

- Cannabis adverse reaction reporting guide for license holders
- Canada Vigilance Adverse Reaction Online Database
- Data on Cannabis Adverse Reactions
- Cannabis and industrial hemp contact information for licence holders, applicants and industry
    - For any questions related to the definitions and examples of various types of adverse reactions or adverse reaction reporting in general, contact the Office of Cannabis Science and Surveillance: cannabis_oss-cannabis_bss@hc-sc.gc.ca
- Online Course for Licence Holders: Cannabis Act and Regulations – Understanding Compliance and Enforcement
    - Registration and account creation required to access the link above

IMPORTANT NOTICE

This letter is intended to support LHs in understanding and complying with the *Cannabis Act* and its regulations. In the event of any discrepancy between this document and the legislation, the legislation shall prevail. For a full understanding of your obligations, please refer to the *Cannabis Act*, *Cannabis Regulations*, and any applicable federal, provincial, territorial, or municipal legislation.

Thank you for your continued dedication to maintaining compliance and supporting public health and safety. We look forward to continuing to work together to ensure a responsible and thriving cannabis industry in Canada.

Thank you,

Health Canada

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