

SOP Title	SOP No.	Version No.	Effective date
Investigating and Reporting Adverse Reactions	QA.SOP-012	00	YYYY/MM/DD

INVESTIGATING AND REPORTING ADVERSE REACTIONS

Written by:	[Name]	Signature/Date	[YYYY/MM/DD]
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1. Purpose

- 1.1. This procedure describes the process by which suspected adverse reactions are reviewed and evaluated to ensure they are reported to Health Canada in a timely manner.

2. Scope

- 2.1. This procedure applies to all suspected and actual adverse reactions reported by a reporter (unsolicited) and through post-marketing surveillance (solicited).

3. Responsibilities

- 3.1. **Customer Service:** Responsible for recording all adverse reaction information received from a reporter and forwarding it to the Quality Assurance Department.
- 3.2. **Responsible Person (RP)/Quality Manager (QM):** Responsible for providing the Minister of Health with a report for each serious adverse event reported, and for maintaining a concise and critical analysis of adverse events occurring each year.

4. Acronyms and Definitions

- 4.1. **Adverse reaction:** A noxious and unintended response to a cannabis product. For reporting purposes, this means that a causal relationship between a cannabis product and occurrence of the adverse reaction is suspected.
- 4.2. **Canada Vigilance Program (CVP):** A Health Canada program responsible for the collection and assessment of marketed health product-related adverse reaction reports.
- 4.3. **Expected adverse reaction:** An adverse reaction whose nature, severity, or frequency is consistent with the description of use on the product label.
- 4.4. **Harmful :** Dangerous or detrimental to health. This effect may be temporary (transitory) or may result in persistent or permanent disability or handicap, or even death.
- 4.5. **Health Care Professional:** A person who is a member in good standing of a professional association of physicians, nurses, pharmacists or other health care; or, a person who has appropriate health care training and therapeutic expertise.

SOP TO BE CONTINUED...