OVERVIEW

You must comply with ACMPR regulations to supply medical cannabis as of August 24, 2016

There are four parts to the regulations – this QuickNote focuses on the Part 1 requirements to be a licensed producer, including:

- Facility design
- Security
- Quality assurance

WHO DOES THIS APPLY TO?

- Licensed producers of medical cannabis in its various forms, i.e., dried marihuana, cannabis oil, fresh marihuana, seeds, plants
- Vendors and Suppliers to the Medical Cannabis Industry (e.g., security firms, packaging & labelling component suppliers, etc.)

KEY POINTS

- Assign a Quality Assurance Person (QAP), who is responsible for quality overview of all aspects of Part 1 Commercial Production before made available for sale, including approving all procedures for producing, packaging, labelling, testing, shipping, and product release. They also address customer complaints, and corrective and preventive actions

- Licensed producers must comply with the entire Part 1 – Commercial Production, in particular, Divisions 1, 4 & 5

Note: Canadian law, as well as European law, including the UK and France, spells ‘marihuana’ with an ‘h.’ The U.S. spells ‘Marijuana’ with a ‘j.’
• Division 1 – Licensed Producers
  o SUBDIVISION A - Authorized Activities and General Obligations
    ▪ Outlines activities that apply to a licensed producer
  o SUBDIVISION B - Licensing
    ▪ A licensed producer must designate:
      • One senior person in charge (SPIC) to have overall responsibility for management of the activities conducted by the licensed producer under their licence at their site — this could be the licensed producer
      • One responsible person in charge (RPIC) to work at the licensed producer’s site and have responsibility for supervising the activities with respect to cannabis conducted by the licensed producer under their licence at that site and for ensuring that the activities comply with the Act and its regulations and the Food and Drugs Act — this could be the senior person in charge
  o SUBDIVISION C - Security Measures
    ▪ You must design your facility security to prevent unauthorized access
    ▪ You must have access controls (i.e., access to areas within a site where cannabis is present must be restricted to persons whose presence in those areas is required by their work responsibilities)
    ▪ The responsible person in charge (RPIC) must be physically present while other persons are in those areas
SUBDIVISION D - Good Production Practices (GPP)

- The QAP is responsible for implementing the requirements of the regulations, not limited to but including:
  - Facility design
    - Flow of material and personnel
    - Equipment & utilities
    - Material of construction
  - Quality assurance system
    - Procedures, quality records, electronic systems
    - Finished product specifications
    - Validated analytical methods
      - Analytical Methods must be validated (e.g., assay, impurities, contaminants, disintegration and solvent residue testing)
    - Accuracy of weight and volume of products must be between 95% to 105%
    - Only use pesticides approved as per the Pest Control Products Act. Note, a pesticide used for food may not be acceptable for medical cannabis
      - Test for pesticide residue on the final product where pesticides are used during production
      - Note: Most recalls are due to pesticide residue issues (e.g., not identified when used)
  - Recall notifications must be submitted to the Minister of Health prior to commencing the recall
SUBDIVISION E - Dried Marihuana Equivalency Factor

- The dried marihuana equivalent is the quantity of cannabis other than dried marihuana that is equivalent to a given quantity of dried marihuana.

SUBDIVISION F - Packaging, Labelling and Shipping

- Packaging/labelling
  - Strict labeling and packaging requirements apply; labeling criteria are based on the form of cannabis.
  - You need Health Canada-approved stability data to assign an expiry date.
  - You must test your product against technical specifications and the QAP must release the product prior to being made available for sale.

- Shipping
  - A producer cannot fulfill more than the equivalent of 150 grams of dried marihuana in 30 days to a patient.
  - Regardless of the amount prescribed, a patient can receive a maximum equivalent of 150 grams of dried marihuana per shipment.
  - The maximum immediate container size is 30 grams.

SUBDIVISION G - Import and Export

- Describes application process for import and export permits.

SUBDIVISION H - Security Clearances

- Your key personnel must pass a stringent security clearance process.

SUBDIVISION I - Communication of Information

- You must provide records to a Canadian police force, if requested.
• Division 4 – Sale or Provision by a Licensed Producer to a Person Other than a Client
  o You can only sell or provide product to a person (other than a client) who is authorized per the regulations, and with a written order

• Division 5 – Record Keeping by Licensed Producers
  o Keep records of all transactions

WHAT DO I NEED TO DO?

• Assign a QAP and key personnel (e.g., SPIC, RPIC) for your application
• Establish and maintain a compliant GPP quality system
• Qualify your Facility Design and Security Design
• Prepare for your Health Canada inspection

DEFINITIONS

• ACMPR
  Access to Cannabis for Medical Purposes Regulations

• Equivalency
  Equivalency in dried marihuana is the quantity of cannabis other than dried marihuana that is equivalent to a given quantity of dried marihuana

• GMPs (Good Manufacturing Practices)
  Health Canada regulations that apply to pharmaceuticals, natural health products, and APIs that are approved for therapeutic use

• GPPs
  Good Production Practices
• Licensed producer
  The holder of a licence that permits possession, production, sale/provision, shipping, transportation, delivery, and destruction of cannabis

• Marihuana
  The substance referred to as “Cannabis (marihuana)”

• Marihuana, dried
  Harvested marihuana that has been subjected to any drying process, but does not include seeds

• Marihuana, fresh
  Freshly harvested marihuana buds and leaves, but does not include plant material that can be used to propagate marihuana

• Quality Assurance Person (QAP)
  A licensed producer must have a QAP who:

  a) is responsible for assuring the quality of the fresh or dried marihuana, cannabis oil or marihuana plants or seeds before they are made available for sale, and

  b) investigates every complaint received in respect of the quality of those substances and, if necessary, takes corrective and preventative measures

  Those substances must be produced, packaged, labelled and stored using methods and procedures that, prior to their implementation, have been approved by a QAP

  Every lot or batch of those substances must be approved by a QAP before it is made available for sale

• RPIC
  Responsible person in charge

• SPIC
  Senior person in charge
Written order

The written order must:

(a) be signed and dated by a person described in subsection (1) or (2) and indicate their name;

(b) indicate the shipping address in Canada; and

(c) specify the substance being ordered and include the following information:

(i) in the case of fresh or dried marihuana or cannabis oil, its quantity and brand name, or

(ii) in the case of cannabis other than cannabis referred to in subparagraph (i), its quantity, description and, if applicable, brand name

RELATED DOCUMENTS

Applications

To obtain an ACMPR Licensed Producer Application Form, you must email: ACMPR-RACFM@hc-sc.gc.ca

Regulations


Quick NOTES

- Authorized Licensed Producers of Cannabis for Medical Purposes

Security

- Directive On Physical Security Requirements For Controlled Substances


Inspections and Licensing

- Application Process: Becoming a Licensed Producer of Cannabis for Medical Purposes

- Improving the Licensing of Production of Cannabis for Medical Purposes

FAQ

1. What is Health Canada’s role?

   Licensing and overseeing the commercial industry (including inspections of Licensed Producers)

   Registering individuals to produce a limited amount of cannabis for their own medical purposes
2. **When can I expect a Health Canada inspection?**

You should expect to provide evidence of a compliant GPP quality system during your application process (detailed review portion)

Health Canada is applying a risk-rating system to determine how often they inspect Licensed producers

There are different types of Health Canada, Office of Medical Cannabis Inspections:

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<td>Successful detailed review application</td>
<td>Security and controls</td>
<td>Licence to produce</td>
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<td>Introduction Inspection</td>
<td>LP Notification that cultivation has begun</td>
<td>Security, GPP Compliance, Licensed conditions</td>
<td>Progression to issuance of Pre-Sales inspection</td>
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<td>Pre-Sales Inspection</td>
<td>LP Amendment application: add “Sale” to license</td>
<td>GPP Compliance, packaging, Labelling shipping</td>
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<td>Routine GPP</td>
<td>LP Annual license review</td>
<td>GPP and License compliance, post-market monitoring</td>
<td>Continued access to grow and sell cannabis for medical purposes</td>
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3. **How is GPP different than GMP?**

Oversight by Health Canada is less defined, but consistent with Health Canada controlled drug procedures, and containing elements of Natural Health Product regulation.

4. **Licensed producers must comply with the entire Part 1 – Commercial Production, in particular, Divisions 1, 4 & 5. What are the other parts of the regulations?**

Division 2 applies to client registration and ordering.

Division 3 applies to clients and other authorized users.

Part 2 applies to production for own medical purposes and production by a designated person

Part 3 applies to transitional provisions

Part 4 applies to consequential amendments, repeal, application, and coming into force

5. **How many licensed producers are there in Canada?**

As of Oct 1, 2017, there are 14 Licensed Producers in BC and 35 in Ontario (62 total in Canada)

Licensing statistics as of May 25, 2017:

- 1665 applications received
- 265 have been refused
- 428 applications are in progress
- 69 have been withdrawn
- 858 were incomplete and have been returned

6. **How do I get a licence? What are the steps?**

Complete the “Application to Become A Licensed Producer Under The Access To Cannabis For Medical Purposes Regulations (ACMPR)”

Your application must demonstrate how the security, record keeping, inventory control measures, and GPP at the facility meet all the regulatory requirements
7. Is a stability program required for medical cannabis products?
   No, unless a labelled expiration date claim is made.

8. What medical cannabis dosage forms are allowed?
   - Dried marihuana – loose or roll
   - Cannabis oil – capsule or similar – additional dose controls apply
   - Fresh marihuana
   - Seeds
   - Plant

9. Do I need to meet Health Canada Good Manufacturing Practices (GMPs) for medicinal products/drugs?
   Yes, if you wish to export to Australia or EU, you will need to meet GMPs

10. What happened to the MMPR regulations?
    ACMPR (Access to Cannabis for Medical Purposes Regulations, SOR 2016-230) for cannabis producers replaced MMPR (Marihuana for Medical Purposes Regulations) as of August 24, 2016

We can help you. Call us today at 1-877-877-5152 ext. 232 or visit www.QualityAndCompliance.com