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GUIDANCE DOCUMENT

Technical Specifications for Testing Dried Marihuana for Medical Purposes

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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in the document, to allow the Department to verify compliance with the quality requirements of the *Marihuana for Medical Purposes Regulations* as well as adequately mitigate the risk of diversion of controlled substances to an illicit market or use.

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1. Purpose

This document is intended to help Licensed Producers (LPs) comply with certain quality requirements in Division 4 of the *Marihuana for Medical Purposes Regulations* (MMPR). Health Canada's Office of Controlled Substances is the authority responsible for licensing and compliance monitoring under the *Controlled Drugs and Substances Act* (CDSA) and MMPR.

2. Background

To date, dried marihuana has not been authorized as a therapeutic product in Canada or in any other country. In addition, no international standards currently exist specifically for the quality of dried marihuana.

Dried marihuana produced by a LP, while exempt from the application of the *Food and Drug Regulations* via the *Marihuana Exemption (Food and Drugs Act) Regulations* other than in the context of marihuana to be used in a clinical trial, is subject to provisions in the *Food and Drugs Act*. This includes a general prohibition (paragraph 8(a) and (b)) against the sale of a drug that was "manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or is adulterated".

Division 4 of the MMPR includes Good Production Practices (GPP) requirements relating to the premises, storage of dried marihuana, equipment, the sanitation program, standard operating procedures, recall of product, and quality assurance personnel. Additionally, the MMPR provide compliance and enforcement measures, allowing for refusal, suspension or revocation of a producer's licence on the basis of risks to public health, safety or security.

3. Scope

The specific regulatory requirements listed in section 5 of this guidance document are applicable to finished dried marihuana which is to be sold or provided by a LP under the MMPR. They do not apply to live plants or to intermediate processing stages. The finished product requirements are also applicable to imported dried marihuana when it is to be sold or provided in Canada, and to Canadian-produced marihuana which is to be exported.

4. Procedures

In order to achieve purity and quality of the finished dried marihuana product, Good Production Practices as outlined in the MMPR must be followed at all stages of production, packaging, labelling and storage of the marihuana.

As specified in the MMPR, each batch or lot of dried marihuana must be approved for release by the LP's Quality Assurance person, who must have the training, experience and technical knowledge relating to the activity conducted and the requirements of Division 4 of the MMPR. This means that the Quality Assurance person must have the ability to evaluate the operations of the LP to ensure compliance with Division 4, and the technical knowledge to be able to assess analytical testing results in order to be able to make the determination of whether the dried marihuana is suitable for sale. The Quality Assurance person is also responsible for investigating quality-related complaints and taking corrective and preventive actions, if necessary.

Visual inspection should confirm the absence of pests or extraneous substances. There is no requirement to mill or irradiate the dried marihuana, although LPs may choose to do so.

5. Specific Regulatory Provisions in Division 4 of the MMPR

MMPR s53. (1) **The microbial and chemical contaminants of dried marihuana must be within generally accepted tolerance limits for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the *Food and Drugs Act.***

Guidance: Schedule B of the Food and Drugs Act [1] lists recognized international publications which set technical specifications for pharmaceutical drugs, herbal medicines, and dietary supplements. LPs must maintain consistent specifications for their products according to these publications, and assess each lot or batch of dried marihuana against those specifications before approving the release of a lot or batch for sale. Note that it is the LP's responsibility to decide on the specifications and methods to be used for testing.

As an example, one potential Schedule B publication which could be chosen is the European Pharmacopeia (EP) [2]. All relevant specifications from the EP would then apply. This would include chapter 5.8.1 (current edition 7.5): "Microbial Quality of Herbal Medicinal Products for Oral Use". In this case, testing for total aerobic microbial count, total combined yeast and moulds count, bile-tolerant gram negative bacteria, *Escherichia coli*, and *Salmonella* would have to be conducted, and the results would have to be below the limits listed in Table C of that chapter before the

product could be released for sale. In addition, testing for aflatoxins must also be conducted, with methods and limits as specified in Chapter 2.08.18 (Determination of aflatoxin B1 in herbal drugs) of the EP. These limits are required to demonstrate that the dried marihuana has been produced under sanitary conditions, and that it is appropriate for human consumption. The general monograph on herbal drugs in this same publication would also apply, with the associated limits on heavy metals.

Other microbial and chemical contaminant limits for herbal medicines from a Schedule B publication are acceptable.

MMPR s53. (2) **Analytical testing for those contaminants and for the percentages of delta-9-tetrahydrocannabinol and cannabidiol referred to in these Regulations must be conducted using validated methods.**

Guidance: Testing of dried marihuana can only be performed by the holder of a producer's licence under the MMPR or of a dealer's licence under the *Narcotic Control Regulations*, and must be performed according to validated methods. Validation means establishing documented evidence that will provide a high degree of assurance that the testing methods must consistently and reproducibly lead to the predetermined specifications and quality results in dried marihuana. Appropriate reference standards and controls should be included in each testing protocol, and LPs must maintain records summarizing testing protocols followed and detailed testing results for each batch or lot of finished dried marihuana.

MMPR s54. (1) **Marihuana must not be treated — before, during or after the drying process — with a pest control product that has not been registered under the *Pest Control Products Act* for use on marihuana for medical purposes.**

Guidance: Under the *Pest Control Products Act* [3], pesticides may only be used if assessed and registered by the Pest Management Regulatory Agency (PMRA) for specific uses.

For more information on registration of pesticides, see the PMRA web site [4].

MMPR s54. (2) **Dried marihuana must not contain any residue of a pest control product in excess of any maximum residue limit specified for the product under section 9 of the *Pest Control Products Act.***

Guidance: During the review of a pest control product by the PMRA, a maximum residue limit (MRL) may be established, depending on the product and the associated risk assessment. If a MRL is established for any pest control product

when registered for use on marihuana for medical purposes, the finished dried marihuana must not contain any pesticide residue exceeding this limit.

6. References

[1] http://laws.justice.gc.ca/eng/acts/F-27/

[2] http://online6.edqm.eu/ep705/

[3] http://laws-lois.justice.gc.ca/eng/acts/P-9.01/

[4] http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php