ACMPR: Same as it Ever Was — With More Options for Patients and Licensed Producers

August 30, 2016

On August 24, 2016, the *Access to Cannabis for Medical Purposes Regulations* (ACMPR) replaced the *Marihuana for Medical Purposes Regulations* (MMPR) as the regulations governing Canada's medical cannabis program. The ACMPR continues (but replaces) the MMPR with changes required by *Allard* v *Canada* (2016 FC 236) by allowing patients to grow cannabis for personal use and codifies Health Canada's response to *R* v *Smith* (2015 SCC 34) by regulating production and sale of cannabis oil. BLG's bulletin summarizing the August 11, 2016 announcement of the ACMPR can be found here.

From the perspective of Canada's 35 licensees, the ACMPR maintains many of the practices required by the MMPR. Provisions new to the ACMPR related to sale of plants and seeds, production and sale of cannabis oil, and research and development are described below. While the ACMPR does not allow for retail distribution at pharmacies, that is an expected next step as regulations on medical cannabis progress. Pharmacies are specifically mentioned in the impact analysis statement (Statement) published with the ACMPR.

Plants and Seeds

Patients interested in growing cannabis may now apply to Health Canada for a registration certificate. Based on a single certificate, a patient may obtain plants or seeds from one or more licensed producers. The patient may also obtain an interim supply of dried marihuana, cannabis oil, or fresh marihuana from one licensed producer. Limits on the number of plants or seeds are based on prescription size and whether the plants are to be grown indoors or outdoors.

As under the repealed *Marihuana Medical Access Regulations* (MMAR), a designated person is permitted to grow on behalf of a patient. The ACMPR limits a designated person to growing for a maximum of two patients, and one site to growing for a maximum of four patients. Patients or designated persons currently growing under the *Allard* injunction may apply for registration under the ACMPR, and once within the ACMPR may change production sites, which was not possible since the repeal of the MMAR.

Cannabis Oil

The provisions relating to cannabis oil codify statements published by Health Canada following *Smith*. Cannabis oil for ingestion or topical use may be prepared and sold to patients. Butane and other organic solvents are not permitted in cannabis oil prepared either by a licensed producer or by a patient for their own use. A maximum concentration of 30 mg/ml total THC and THCA applies to cannabis oil that is sold without a dosage form and a maximum of 10 mg total THC and THCA per dosage for cannabis oil sold in capsules or a similar dosage form.

A restrictive departure from the Health Canada statements provides that the *only* authorized dosage form for cannabis oil is a capsule or similar dosage form (although cannabis oil can be sold without a dosage form, consistent with the practices of licensed producers following *Smith*). As such, the ACMPR does not allow for edible or other infused products including cannabis oil to be sold to patients.

The ACMPR also permits licensed producers to sell cannabis, *other than marihuana or cannabis oil*, to other licensed producers for producing cannabis oil. This establishes a regulatory basis for sale of leaves trimmed from flowers during harvesting and processing of cannabis. In some U.S. markets, such trimmed leaves have become a valuable commodity traded between growers and infused product manufacturers as a starting material for preparing cannabis oil.

Research and Development

The ACMPR includes new record-keeping requirements specific to research and development. Such records must document any product or compound containing cannabis prepared for research and development.

While the regulations on sale of cannabis oil in dosage forms are restricted to capsules or a similar dosage form, the broader language of the record-keeping provisions provide a basis for licensed producers to prepare and study other products or compounds containing cannabis (e.g., infused products) for research and development. Many licensed producers currently advertise their research and development programs. Given the variety of products available in U.S. states with medical or adult use laws, facilitating complementary and competitive research in Canada is a step in the right direction for Canadian patients, researchers, licensed producers, and other businesses.

What Does the Future Hold?

As described in detail in the Statement, the ACMPR is an interim regulation. The small amount of time available for preparing the ACMPR prompted a combination of the MMPR, the MMAR, and regulation of cannabis oil specifically as required by *Smith*, as the only practical solution.

We expect more clarity on what the future holds for licensed producers and other industry participants with the release of the November 2016 report from the Task Force on Marijuana Legalization and Regulation. The Statement suggests that pharmacies may play a role in the medical cannabis supply chain in the future, but that addressing

differing provincial regulations was not possible in the time frame available. The only role for pharmacists provided for in the ACMPR is in connection with receiving orders from a licensed producer on behalf of a hospital, as in the MMPR.

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