

## PRACTICE GUIDANCE: DISPENSING MIFEGYMISO®

### Introduction

In June 2015, Health Canada approved the drug product Mifegymiso® for non-surgical abortion in Canada. Unlike most drug approvals, Health Canada's approval included a Restricted Distribution Program, which has become the focus of much discussion and differing views between various provincial pharmacy and medical regulatory authorities and Health Canada. While the sale of the product in Canada began in January 2017, discussions between Health Canada, the manufacturer and the professional regulatory bodies regarding the practice of medicine and pharmacy in providing this medication have been ongoing.

The Nova Scotia College of Pharmacists provides the following guidance to pharmacists and pharmacy technicians when dispensing Mifegymiso® so that unnecessary barriers for patient access can be avoided and appropriate safeguards for patient safety are in place.

### Guidance

#### **Release of the Medication**

On its website, Health Canada states that, "Prescribers stocking MIFEGYMISO may dispense the medication directly to the woman, where permitted under provincial/territorial law. Alternatively, a prescriber may send a prescription (by fax, verbal prescription or written prescription) to a pharmacy that stocks MIFEGYMISO. The box may then be shipped back to the prescriber office for delivery to the woman." However, Health Canada also qualifies this statement with the following, "Information beyond [this] ... is considered to be practice of medicine / pharmacy and will vary by province as it falls under the jurisdiction of the provincial professional colleges."

As with any prescription, it is the primary responsibility of the pharmacist to determine the appropriateness of drug therapy. In determining whether a prescription for Mifegymiso® is appropriate to dispense, the pharmacist

needs to consider whether they are satisfied that the mifepristone is being “administered under the supervision of a physician” (as directed in the product monograph); and that otherwise, they do so as an exercise of professional judgment that they can reasonably defend, bearing the professional responsibility for that decision.

In making this determination, the pharmacist should consider the differing interpretations of “administered under the supervision of a physician” provided by Health Canada and the College of Physicians and Surgeons of Nova Scotia:

Health Canada (*Mifegymiso*®: *Myths vs. Facts*):

*Fact: The requirement for medical supervision means that the doctor must provide the medication to the patient directly, and have further discussions regarding the effects and possible risks. Medical supervision is required, however, it is not mandated that the medication be swallowed in front of the physician.*

The College of Physicians and Surgeons of Nova Scotia (CPSNS, regulator of the practice of medicine in Nova Scotia) states in their professional standard:

*When prescribing Mifegymiso, physicians must:*

- a) Give the prescription to the patient to take to the pharmacy of her choice to receive the medication directly from the pharmacist; or*
- b) Give the prescription to the patient to take to the pharmacy of her choice, for delivery back to the physician, and then given by the physician to the patient.*

Given the CPSNS’ practice standards, pharmacists who receive a prescription for Mifegymiso from a patient can assume that the physician intended for it to be dispensed to the patient directly (as per the usual practice for other drug therapy), unless the physician specifically directs otherwise.

## **Informed Consent**

It is particularly important that pharmacists are satisfied that each patient has provided informed consent through robust discussion with their physician.

## **Collaboration**

While interpretations of “under the supervision of a physician” vary somewhat, it is nonetheless critical that in providing Mifegymiso® to patients, there is clear, interprofessional communication regarding the directions for consumption, and the responsibility and accountability for informed consent, counselling, assessment, monitoring and follow-up.

At a local level, pharmacists are encouraged to communicate with physicians in advance regarding whether they are willing and competent to participate in providing Mifegymiso® to patients. Participating practitioners must use a collaborative process that will ensure the care provided is patient-centered, does not create unnecessary barriers to access, and provides appropriate safeguards for patient safety.

Given the time-sensitive nature of medical abortion, pharmacies should have a plan in place that protects patients' rights to access high-quality health services and upholds individual providers' rights to conscientious objection.

## **Competency**

It is the professional responsibility of a pharmacist to ensure that they have the knowledge and skills required to competently provide Mifegymiso®. The following educational resources are available to support the pharmacist in meeting this responsibility:

*Mifegymiso® Summary Basis of Decision*, Health Canada, 2016

*Accredited Medical Abortion Training Program*, Society of Obstetricians and Gynaecologists of Canada, 2016

## **Resources**

General product information and forms, Celopharma, Inc. [www.celopharma.com](http://www.celopharma.com)

Additional resources for providers are available through Canadian Abortion Providers Support :  
[https://www.caps-cpca.ubc.ca/index.php?title=Main\\_Page&oldid=36](https://www.caps-cpca.ubc.ca/index.php?title=Main_Page&oldid=36)