

# DISPENSING MIFEGYMISO®

*Guidance for Pharmacy Professionals Who Are  
Dispensing Mifegymiso®*



**Ontario College  
of Pharmacists**

Putting patients first since 1871

**UPDATED ON: August 23, 2017**

## Purpose

To provide guidance for pharmacists and pharmacy technicians when dispensing Mifegymiso®.

## Introduction

Health Canada originally approved the drug Mifegymiso®, a two-drug combination product that provides a non-surgical option for early abortion in July 2015. Mifegymiso® became available to the Canadian public in January 2017.

Details provided by the manufacturer and Health Canada regarding requirements for physician dispensing and patient ingestion of the medication were unclear and there was concern that patient access to therapy could be impaired. As such, both the Ontario College of Pharmacists (OCP) and the College of Physicians and Surgeons of Ontario (CPSO) expressed concerns to Health Canada that these requirements were outside of the normal distribution system for medications in Ontario and would be challenging to operationalize. Although physicians in Ontario can dispense drugs according to the CPSO's [Dispensing Drugs](#) policy, only a small number of physicians dispense medications as part of their practice.

After corresponding with Health Canada, OCP and CPSO were advised that the product monograph is not a legally binding document. If, under the practice of medicine or pharmacy, the administration or distribution of the medication is outside of what is approved in the product monograph, the product would be considered to be used off-label.

## Options for Dispensing Mifegymiso®

Both the OCP and CPSO have confirmed there are three possible ways Mifegymiso® can be provided to patients who are prescribed the drug.

### *Options consistent with Health Canada stipulations:*

- Patients can take the prescription to a pharmacy of their choice and have the medication delivered to the physician's office, or
- Physicians can sell and dispense the medication to the patient in accordance with CPSO's [Dispensing Drugs](#) policy.

### *Direct Patient Dispensing Option:*

- Patients can take the prescription to a pharmacy of their choice and have the medication dispensed directly to the patient.

It is within the scope of practice of pharmacists in Ontario to dispense medications directly to patients, therefore in alignment with [provincial legislation](#), pharmacists are able to dispense Mifegymiso® directly to the patient.

## **Administering and Ingesting Mifegymiso®**

The product monograph outlines that the drug should be “administered under the supervision of the prescriber” and instructs patients to take Mifegymiso® “as directed by their doctor or given to them by medical staff”. Health Canada provided clarification that the intent of the wording in the product monograph is to allow prescribers to use their discretion for each individual patient and does not mandate that the medication be ingested in the presence of the prescriber. Determining details of medication therapy is a treatment decision between the physician and patient.

## **Communication between Physicians, Patients and Pharmacists**

Physicians will be required to determine with the patient how the medication is to be dispensed and where it is to be ingested. The dispensing option selected will be communicated to the pharmacist at the time of prescribing. When dispensing Mifegymiso®, the pharmacist must be aware of and understand the dispensing option the physician and patient determined would be appropriate.

## **Pharmacist Training**

It is the professional responsibility of a pharmacist to ensure that he or she has sufficient knowledge, skills and abilities to competently dispense any medication. A pharmacist must ensure that he or she has undergone the appropriate training and has the required resources to evaluate the potential risks and benefits, and any other relevant factors specific to the situation, to ensure the drug is appropriate for the patient. An education program has been developed by the Society of Obstetricians and Gynaecologists of Canada, the College of Family Physicians of Canada, and the Canadian Pharmacists Association.

The course is available to physicians and pharmacists through the e-learning portal of the Society of Obstetricians and Gynaecologists of Canada (<https://sogc.org/online-courses/courses.html/>).

## **Responsibilities When Dispensing**

Given the serious safety concerns identified with the use of Mifegymiso, pharmacists are reminded that, as with any medication, they are responsible for providing appropriate follow-up and ensuring that the patient is provided with relevant and sufficient information about the medication, including how to manage risks associated with use. Pharmacists are also required to report any cases of serious or unexpected side effects to Health Canada’s MedEffect Canada adverse reaction reporting system.